RISK BASED DECISIONMAKING AT THE ENVIRONMENTAL PROTECTION AGENCY

HEARING

BEFORE THE

ENVIRONMENT, ENERGY, AND NATURAL RESOURCES SUBCOMMITTEE

AND

LEGISLATION AND NATIONAL SECURITY SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

FEBRUARY 1, 1994

Printed for the use of the Committee on Government Operations

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RISK BASED DECISIONMAKING AT THE ENVIRONMENTAL PROTECTION AGENCY

TUESDAY, FEBRUARY 1, 1994

HOUSE OF REPRESENTATIVES, ENVIRONMENT, ENERGY, AND NATURAL RESOURCES SUBCOMMITTEE, AND LEGISLATION AND NATIONAL SECURITY SUBCOMMITTEE OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, DC.

The subcommittees met, pursuant to notice, at 10 a.m., in room 2154, Rayburn House Office Building, Hon. Mike Synar (chairman of the Environment, Energy, and Natural Resources Subcommittee) presiding.

Members present: Representatives John Conyers, Jr., Henry A. Waxman, Mike Synar, John M. Spratt, Jr., Karen L. Thurman, James A. Hayes, Corrine Brown, William F. Clinger, Jr., Al McCandless, Craig Thomas, Dick Zimmer, John M. McHugh, John L. Mica, and Bernard Sanders.

Staff present from the Environment, Energy, and Natural Resources Subcommittee: Sandra Z. Harris, staff director; Ruth Fleischer, counsel; Sheila C. Canavan, professional staff member; and Elisabeth R. Campbell, clerk.

Full committee staff present: Frank Clemente, senior policy advisor; Marilyn F. Jarvis, staff assistant; Judith A. Blanchard, minority deputy staff director; and Charli E. Coon, minority professional staff.

OPENING STATEMENT OF CHAIRMAN SYNAR

Mr. SYNAR. Today the Subcommittee on Environment, Energy, and Natural Resources and its sister Subcommittee on Legislation and National Security are holding a hearing on the subject of risk analysis and risk management at the Environmental Protection Agency [EPA]. This issue is not new to Congress nor to the executive branch.

To get the benefit of this hearing, it seems to me that we must all be talking from the same page. When we discuss risk at EPA, we must all mean the same thing and use the same terms.

Risk assessment, risk management, comparative risk analysis, risk communication, and cost benefit all have very distinct meanings. I hope these meanings will be clear by the time everyone leaves here today.

Risk analysis is not magic. It is just one tool used by decisionmakers. Like any tool, it can be abused. It can be politicized. And members can blame too much or too little risk analysis

for whatever they think is wrong with EPA—from priorities to specific programs. But remember, it is only a tool.

I expect to hear EPA attacked today for having the wrong priorities, for spending its money and manpower on lower risk activities instead of big-ticket items. But who gave the Agency its priorities, and who approves the Agency's budget? We do. And if the priorities are wrong, the Congress must take a good deal of the responsibility.

If the Agency spends too much on Superfund and not enough on something else, we can change that. For the most part, the Agency can't. Court orders and citizen suits ensure that EPA follows the directions we set. This is what Congress intended.

These "misplaced priorities" are often blamed on a misinformed public and what they see as serious risks. And anyone who thinks Congress can or should ignore the views of the people who elect us is a fool. Therefore, it seems to me that one solution is to improve education about environmental risks.

We all support weighing the benefits of one EPA program against another for funding purposes. This kind of analysis is what we do every day—from calculating health care needs to cutting unneeded weapon systems. But how can EPA, and how can we, choose between spending scarce resources on preventing retardation in children from lead poisoning and preventing cancers or birth defects from other poisons?

These are not just scientific issues—they are policy issues as well. And we must be careful before we turn these important questions over completely to technicians who are not accountable to the public.

I will close essentially where I started. As important as it is, risk analysis is not magic. And in my view, we will compound rather than fix EPA's problems if we try to pretend that more risk analysis is the simple solution to all that troubles EPA.

At this time I'd like to call on my dear friend Bill Clinger for an opening statement.

Mr. CLINGER. Thank you very much, Mr. Chairman. I'm pleased to have the opportunity this morning to participate in this hearing so that we can discuss some of the admittedly contentious issues surrounding EPA's use of risk assessment and cost-benefit analysis.

In terms of environmental success stories, the picture, I think we would have to agree, is somewhat bleak and it is cause for concern. As you know, we are spending billions on the environment and costs are spiraling upwards rapidly.

According to EPA's cost of a clean environment report, by the year 2000 it is projected that 2.8 percent of GNP, or close to $200 billion will be allocated to cleaning up the environment. Perhaps this wouldn't be so bad if we saw results, good results, but unfortunately, in many instances there is no apparent improvement in either the environment or in human health.

As we know, we are hearing the desperate pleas from State and local governments that are going bankrupt because they cannot afford to implement all of the unfunded environmental mandates. There is no money left over for priorities like schools, public health, crime prevention, and others.

Industry is concerned because of the impacts of environmental regulation on the economy. Many small businesses cannot continue to operate because of the burden of implementing numerous environmental regulations or regulations that conflict or are redundant.

There is a cry for rational and objective decisionmaking without the emotional hue. We are learning that we can't do it all, so we must prioritize, and one way to do this is to base our decisions on risk.

Can we afford to spend millions on one potential death averted? Risk assessment is viewed as an important tool to help prioritize resources. It is also viewed as a tool to help us understand what our alternatives may be before we choose a single path of regulation.

In a study conducted by EPA looking at the use of risk assessment and cost-benefit analysis for regulation, the findings of the report indicate that these analyses improve environmental regulation and often reveal regulatory alternatives that achieve the desired degree of environmental benefits at a lower cost. I'm sure that we're going to hear from some witnesses today about concerns in using risk assessment and cost-benefit analysis.

There is no magic bullet, as you've indicated, Mr. Chairman. However, science will continue to evolve and risk assessment will become more sophisticated over time. Using a tool that is less than perfect is preferable to using no tool at all. We cannot continue to stumble in the dark, as we have been. Risk assessment, I think, is one means to shed some light on these issues and help us gain back public confidence in the environmental regulatory process.

Thank you very much, Mr. Chairman. I look forward to hearing from our witnesses.

Mr. SYNAR. Thank you, Mr. Clinger. One of the leaders on this subcommittee on this very issue is our colleague from California, Mr. Condit.

Mr. CONDIT. Thank you, Mr. Chairman.

First, I would like to commend Chairman Conyers and Chairman Synar for calling this important hearing. I have examined the witness list and I'm impressed with the level of experience of the witnesses.

I'm sure we will hear a thorough and balanced presentation of the issues surrounding risk-based decisionmaking today. I would also like to commend President Clinton for the principles outlined in his Executive order on regulatory planning and review, which is among the topics of today's hearing.

I have met with the first witness, Sally Katzen, to discuss this order and I look forward to her testimony today. It is my intention to introduce legislation based upon this order within the next few weeks. I think that risk-based regulation with an emphasis on cost and benefit is both the prudent and necessary course.

By basing my legislation on the Executive order, I am responding to the critics of risk amendments of the EPA bill by offering a comprehensive nonpiecemeal approach to this issue.

The introduction to this order sums up my feeling quite well. It says, "The American people deserve a regulatory system that works for them, not against them, a regulatory system that protects and improves their health and safety, environment and well-being, and

improves the performance of the economy without imposing unacceptable or unreasonable costs to society."

It would be wonderful if Congress and the executive branch could regulate without regard to cost incurred or the risks involved, but that would ignore the financial and practical realities that business, associations, and yes, even government face.

The intent of risk analysis and cost-benefit estimates relates to the need to develop and distribute accurate, objective, and timely information on the risk involved and cost incurred in the rulemaking process.

This is not some evil creation designed to undermine the rulemaking process. This is simply an attempt to apply some advance consideration to the cost and to the consequences of Federal regulation.

I can assure you that the mayors, Governors, and legislators in your States and districts are interested in access to this knowledge. They, of course, are interested in comparative risk and cost-benefit analysis because they must balance their budgets.

For this reason, I am very supportive of the administration's intent in the Executive order on regulatory planning and review. However, I have some concerns about its implementation and the extent to which certain agencies intend to comply.

Several months ago I had a very productive meeting with Ms. Katzen, and at that meeting she outlined the principles of the Executive order and why the administration had issued it. Since that time, I have met with other Federal officials who have expressed a reluctance to adhere to the principles outlined by that order.

Because of this apparent reluctance, I have decided to draft legislation to codify the order. If enacted, it would have both the clout of law and show the intent of Congress on these principles. The implementation of this Executive order would require a new way of thinking on the part of the agency that issues the regulation.

For example, how do we assure that risk analysis conducted for a proposed rule does not become a self-fulfilling prophesy, overstating the risk in order to justify the regulation? Perhaps we need to analyze some form of peer review process that could be implemented to prevent this.

I am hopeful that today's witness will have some thoughts on these issues. I would also like to take this moment to thank EPA Administrator Carol Browner for very graciously coming to California last month. She met with many of my constituents and other people throughout the State on risk and other issues of concern.

I would ask for unanimous consent to submit for the record testimony prepared by Mr. Walter Murray of the Stanislaus County Manufacturers Association. I thought some very important issues were raised during Ms. Browner's visit, and this testimony represents a summation of them.

I would also like to ask, if I may have unanimous consent, to add a letter to the record from the National Association of State Departments of Agriculture.

Mr. SYNAR. Without objection, both of those will be submitted for the record.

[The material can be found in the appendix.]

Mr. SYNAR. Let me thank you again, Mr. Condit, for your leadership in this area and please include me as an original cosponsor of the codification of the Executive order. I think it goes in the right direction.

Mr. McCandless from California.

Mr. MCCANDLESS. Thank you, Mr. Chairman. I appreciate your holding this hearing on the benefits of environmental risk assessment. I would also like to thank my colleagues, Congresswoman Thurman, Congressman Mica and Congressman Condit for their work in placing this important issue before the committee.

I come from a district which has been paralyzed by runaway environmental regulation. A desert with a booming population, we have been hamstrung in our efforts to make the best use of our limited resources by ill-conceived and unyielding environmental rules.

In the past year alone, we have been prevented from making secondary necessary use of tertiary-treated waste water by regulations which prohibit dry stream bed releases, based upon a study conducted, if you will, in the Great Lakes.

We have been unable to continue reconstruction of California's deadliest highway by regulations which have EPA and the Corps of Engineers wrangling over the possibility of wetlands in the desert—197 acres of wetlands in the middle of the Colorado desert?

We have been unable to build much-needed housing, schools, and infrastructure due to the possible listings of the Riverside Fairy Shrimp, the Orange-throated Whiptail Lizard, and the Flower-Loving Fly as endangered species.

While I certainly recognize the importance of protecting our environment from real and serious threats, I do question the need for regulations which harm more than they help and which affect all communities, while targeting a few. Clearly, there is a strong and biding need for environmental risk assessment, and I, for one, will support it. Thank you, Mr. Chairman.

Mr. SYNAR. Mr. Hayes of Louisiana.

Mr. HAYES. Thank you. I would like to associate myself with Mr. Condit's remarks regarding his legislation, and would like to make two points.

One is that when we talk about risk assessment and we talk about a quantitative approach, and that is the same thing we'd be doing in the Army Corps of Engineers or anyone else, when we look at cost-benefit ratios, the question suddenly comes back, when you're dealing with health and human life, and you can't have cost-benefit ratios because there is no amount of money that impacts that.

Well, we do that every day. The Corps of Engineers is a good example. So is the highway department. I assure you that there are people who will die because Highway 171 in Louisiana is not four-laned. I also assure you the cost is gigantic, but it's measured in those terms. There are intersections that would be repaired in cities that cost tens of millions of dollars. Someone will be killed there.

So the idea that this is a separate and completely distinct issue is certainly illusory. The fact of the matter is the same concept of

public health and safety impacts lives, whether it's environmental or whether it's structural.

What we have to put in place is a system that quantifies that to a degree where the public policy choice can be made with sanity and where the cost, and this is the second point I want to make, where the cost includes the cost to society, as well, because unlike the bridge or road or a sidewalk, the cost to implement must be determined in order to understand the full impact.

And the ultimate impact of the two points I've made is this: you can't leave a small community or a large city or a rural area with conflicting mandates from the Federal Government and no ability to pay any, and the inability to rank them. You can't take a small Louisiana community and say you've got to have a sewage system that needs repairs—no question about it. You've got to have pipelines moving water, in violation of the Clean Water Act, is important as a health requirement—no question about it. You've got asbestos in some schools back to the 1950's when you didn't know any better. It's got to be removed—no question about it.

And guess what you also don't have. You don't have a population more than 1,200 and a tax base more than $1 million. Those choices can only be made when you rank the order in which they can be done and recognize they will give you the town. You don't have leverage over a community with 1,200 people and no tax base. You don't have threat of incarceration. You don't have any stick with which to bring them in line when there are only mandates and no resources, and the only loans and grants that used to exist are cut back by budget constraints.

That, I think, should be the theme as we go forward with the hearing today. Not just that we're talking about public health, but that we're talking about the means by which compliance can be made in a sane world that goes through risk as priorities, and that allows choices to be made in a forum in which all parties can understand the impact of the alternatives.

And if our answer is that they cannot be separated and ranked, then the Federal Government has got to be real good at budget and tax increases, because if you want to pay for everything you've mandated, including only a part of the share on business, you have no idea how cheap health care and budget reduction is. Thank you, Mr. Chairman.

Mr. SYNAR. Mr. Mica of Florida.

Mr. MICA. Mr. Chairman, I, too, want to echo the sentiments of others and thank Chairman Conyers and yourself for holding this hearing. But let me say that I feel, quite frankly, that this hearing should not be an excuse for action by the Congress on this important matter.

Let's face it, folks: this may be the last chance that we get to take some congressional action most likely in the 103d Congress and probably in this decade because there are people who oppose any action by the Congress, who want to put this back in the closet where it's been for so many years.

Let me say also that the forces to oppose this now include, of course, the President, the Vice President, the First Lady, and someone with no self-interest, of course, the EPA Administrator. And they have really done a job in trying to get people to delay ac-

tion that may be inevitable and our only chance for action will be this week.

But let me say I don't think that they can forever defy the will of the Governors, the State officials, the county officials, the local officials, and, most importantly, this issue has now caught the imagination of the American people.

We've seen that we may have no other opportunity, really, to curtail the forces that are bankrupting our State and local governments and putting our businesses and industry and agriculture out of business and, more importantly, in a less competitive mode. We can talk about Executive orders, but we all know Executive orders don't have the force of law, and that's one of the major tasks of this Congress.

We have heard countless hearings from EPA and it's been studied day and night and up and down and backward and forward, and the only thing that's going to bring that agency into some focus and some purpose and to fulfill its original mission of protecting the health, safety, and welfare of the citizens of this country is some focus. And we know that a risk assessment action by this Congress is the only thing that's going to accomplish that.

And let me say that this issue is not going to go away. There will be a Waterloo, I can guarantee you right now, with the clean air and water bills. There will be a Waterloo at Superfund and every other juncture that we have.

Finally, let me submit for the record, if I may, letters from the National Governors' Association, which has been meeting here, and their comments, the National Conference of State Legislators, the National Association of Counties, National Federation of Independent Business [NFIB], the American Farm Bureau Federation, the National Association of Home Builders, the National Association of State Fire Marshals, the Fertilizer Institute, several local and inner city groups that are concerned about the waste of resources, needless waste of resources. One is the National Association of Neighborhoods, and we have several other groups of that nature, and the National Association of State Departments of Agriculture.

This is just a sampling that we'll submit at this point for the record. Thank you, Mr. Chairman.

Mr. SYNAR. Without objection.

[The material is filed for the record in the subcommittee office.]

Mr. SYNAR. Mrs. Thurman from Florida.

Mrs. THURMAN. Mr. Chairman, I'll make my statement very brief. I first want to thank you for holding this hearing and putting together what I think are going to be some exceptional panels, giving us both sides of this issue.

I don't think anybody on this committee can misunderstand how strongly I feel about this issue. I think this hearing is definitely the right direction for this Congress to take. And I really believe this is a very timely hearing, as we get ready to debate the elevation bill. I know that's where part of the controversy is; however, I believe it should be included in that.

So I look forward to today's remarks so that we have some testimony before us that shows that we are on the right track.

And second, I would just like to be associated with the comments that Mr. Condit made. Thank you.

Mr. SYNAR. Mr. Hastert.

Mr. HASTERT. Thank you, Mr. Chairman. I also thank the chairman of the full committee, Mr. Conyers, for leading this effort.

I'm equally pleased to see our committee address the topic of risk assessment. There's a growing consensus that the Federal Government has to do a better job of weighing the costs and benefits of legislation and related regulations it hands down. We have to have better data on how our actions will impact the ability of Americans' businesses to grow and to create jobs. We also need to keep an eye on what effect the regulatory burden is having on State and local governments. In short, we need to prioritize better.

Clearly, some Federal regulations are necessary such as those that truly protect public health and safety. However, all too often it's emotion, not science, that drives public policy in Washington. Feel-good policies lose their luster when we realize that the cost manufacturers, wholesalers, shippers, and storefront business owners pay to comply are passed on to all of us, the consumers.

I know that I'm not alone in viewing this as a hidden tax on goods and services and products, and, like all regressive taxes, it hits the poor in this country the hardest.

There's another side to this issue that's equally important. The regulatory burden on State and local governments translates into higher taxes at the local levels. Indeed, it's often the Governor or the mayor or the village president who has to make sense of all the laws and regulations that come from Washington. However, unlike Federal agencies and committees of Congress, State and local officials do not have the luxury of focussing only on environmental issues, or on transportation, or on crime, or on education.

Moreover, every dollar that local governments spend to comply with a nonessential environmental mandate is a dollar taken away from a community's police budget or from its schools. I think that it's important that we keep these things in mind in order to make informed and effective environmental policy. And again, Mr. Chairman, I thank you for bringing this issue forward.

Mr. SYNAR. Mr. Conyers.

Mr. CONYERS. Thank you very much, Chairman Synar. I want to commend you for the briefing memorandum that we had distributed between our two committees. Our colleague, Mr. Waxman, would be with us today. He's chairing another meeting. And I'm delighted to see our senator joining us, as well.

It's a pleasure that we're doing what I promised Gary Condit we would do, that we would break this out, this subject matter out, and take a good, fair, impartial look at it. And that's what we want to do here. And both of these subcommittees have worked very hard to do that.

Risk assessment is with us. It's complemented with cost-benefit analysis. We are asking ourselves the kinds of questions that I think are really critical. How scientific is cost-benefit analysis? Are there other ways of addressing the regulations which might be unfair or that unwisely burden certain populations?

These are real questions. Whether we should put them onto an elevation bill or whether other committees of jurisdiction—and believe me, I do hear from other committee chairmen in the Congress about their interest in this subject, as well—are all matters that

are before us now, and I'm very pleased that this hearing has a set of witnesses that meets everybody's approval. And I want to get on with this hearing. I thank you very much.

Mr. SYNAR. Thank you, John. I thank you and your staff for your efforts in this joint hearing today. Mr. Thomas.

Mr. THOMAS. Thank you, Mr. Chairman. I'll submit a statement and be very brief. Interesting topic, it seems to me. Everyone, when they talk to folks from home—mayors and Governors—would agree that we have a problem we don't do much about. No one would argue that we shouldn't have a cost-benefit decision in regulations, but we don't do much about it.

Nobody would argue that we ought not have one-size-fits-all kinds of programs that are the same in Chugwater, WY as in Chicago, but we don't do much about it.

We have a chance, I think, to make some variations in the law for small towns. Chugwater doesn't deal with its solid waste the same as a city. We need to do something about that.

Pinedale has better water than you have in your bottle in your office, but EPA requires them to do more, spend $1½ million for 1,100 people. We ought to do something about that.

So, Mr. Chairman, we have to make decisions and priorities and set priorities and risks on everything we do. No reason why we shouldn't do it here. I hope we move forward and don't just talk about it, as we have in the past. Thank you, sir.

Mr. SYNAR. Thank you. Mr. McHugh from New York.

Mr. MCHUGH. Thank you, Mr. Chairman. Very briefly, let me add my words of appreciation to you and to Mr. Conyers, chairman of the full committee, for bringing this matter forward. As has been stated here repeatedly, this is obviously an issue of great concern.

Speaking as someone who has, within the past year, been at the State level and dealing with localities, I can state very clearly that this is an issue that has not only grabbed the attention but, in fact, demanded the full resources of local governments throughout this Nation.

I think it is our responsibility as a Congress to act very directly and to ensure that the legislation in fact, deals in a direct, forthright manner on the question of risk assessment. I'm appreciative for this opportunity and thank you again.

Mr. SYNAR. Thank you. Mr. Zimmer.

Mr. ZIMMER. Thank you, Mr. Chairman. I also want to thank you and the chairman of the full committee for this opportunity to explore an extremely important issue.

We all wish we had unlimited resources so we could immediately eliminate every potential and actual risk to human health in the environment, but we don't. So the public and private sectors must address these risks with limited budgets. Choices must be made.

The question is how to save the most lives, prevent the most illnesses and protect or restore our environment to the greatest extent possible with available public and private resources. I believe the answer is through sound, scientific assessments of the dangers we face and resource allocation based on the results of those assessments.

We must also engage in a continuing and frank dialog with the American public regarding which threats are most urgent, a difficult challenge when perceptions run counter to reality.

The Committee on Government Operations took a step in this direction when it adopted my amendment to H.R. 3425 to establish an Office of Environmental Risk within the new Department of Environmental Protection. So did the House when it included my "worst first" amendment in the EPA authorization bill we passed late last year.

In spite of these endorsements of the general goals of risk assessment, a great deal of confusion and apprehension remain about the real meaning of terms like "risk assessment," "cost-benefit analysis," and "comparative risk."

So I regard today's hearings as an opportunity to address these concerns. We need to identify the areas of consensus and the matters in dispute. The fact is that both the House and Senate versions of the EPA elevation bill address these issues. We can no longer duck them or finesse them. Let's give clear direction to the administration on the areas of agreement and, more specifically, define the issues that need further debate in this body.

But let's not lose sight of the larger issue. The process of risk assessment, honestly used, will give the Nation the tools to understand the dangers we face and make policies based on objective analysis, rather than emotional impulse. Honestly used, the process will better serve the environment, save more lives, and minimize the burden to our economy and our taxpayers.

Mr. SYNAR. Thank you, Mr. Zimmer, for that very wise statement. And that prompts me to remind members that in the hearing packets before you there is a memorandum from Mr. Conyers and me with respect to this hearing. And I direct your attention to the terms "risk assessment," "risk management," "comparative risk analysis," "risk communications," and "cost-benefit," because each one of those words, as Mr. Zimmer pointed out, has distinct meanings. And I hope that as we proceed through this hearing today, we recognize those distinct differences because they will help us come to some conclusions.

And now, straight from the other side of the building, our dear friend and colleague, Senator Johnston. Senator, we're glad to have you here and we look forward to hearing from you today.

STATEMENT OF HON. J. BENNETT JOHNSTON, A U.S. SENATOR IN CONGRESS FROM THE STATE OF LOUISIANA

Mr. JOHNSTON. Mr. Chairman, thank you very much for the opportunity to testify on this bill.

A number of your members today alluded to the fact that there is a rising tide of protest around the country about regulations, the cost thereof, the burdens that they put on local governments and on people and on industry and what they do to the competitiveness of this country—a tremendous cost.

Now, part of the reason for that, I submit, Mr. Chairman, is that we have not properly evaluated risk, and we have not used science properly.

Now, last year, when this bill, the EPA elevation bill, came on the floor of the Senate, there were a number of different amend-

ments proposed, some which went, I think, too far. Senator Dole had one relative to private property rights, and you can imagine what it said. I think most of you are familiar with the various formulations of the private property rights amendment.

I thought it went too far and so I wrote an amendment that pertained to risk assessment, very narrowly tailored, and proposed it in lieu of the Dole amendment or others on private property. The amendment attracted some attention. Mr. Jack Quinn, who was, I think, the chief of staff of the Vice President, came down to meet with me, along with representatives of EPA, Carol Browner at one time, the Environment and Public Works Committee, and we massaged very carefully all the language of my amendment.

Specifically, we very carefully massaged the language and limited the language with respect to lawsuits. The certificate with respect to risk assessment was to be a certificate containing the four points, but was not to be the stuff of a lawsuit. I had it, I thought, fairly clearly stated, but Jack Quinn, who's a very good lawyer, proposed some further tightening language, so that it was absolutely clear that this certificate would not be the basis of a lawsuit or a cause of action.

And based upon that, the administration embraced and endorsed my amendment. And it passed in the U.S. Senate by a vote of 95 to 3. There was a lot of discussion about it, and all of it was good.

So you can imagine the surprise when I found that this amendment, having been endorsed by the administration, having been embraced by all the pertinent parties, suddenly became a bad amendment which was going to cost billions of dollars, slow down the process, lead to lawsuits and provide all manner of difficulty for the United States. Those who say that, I submit, Mr. Chairman, do not understand the amendment.

Now, why risk assessment? What's the problem? Well, I think the problem is well known to everyone. I mean, it's come to me directly in my Committee on Energy and Natural Resources. I mean, one regulation proposed was going to limit carbon 14 emissions to 1/6,300th of the amount of carbon 14 contained in the body naturally. In other words, the body contains carbon 14 but it was going to be limited to 1/6,300th of that which is in the body naturally.

You know what that was going to cost the taxpayers in the United States? $3,200,000,000. I mean, the list goes on.

Judge Breyer is here and will give you an anecdote which he testified to us about, about children eating small amounts of dirt on a particular—that's on the Ottati case—Judge, I hope I'm not taking all your glory here, but it was such a good example—where to clean up the last 10 percent of waste from a toxic dump costs $9.3 million, and the difference was that before that, children could eat that dirt for 70 days without difficulty, and after the expenditure of the $9.3 million they could eat dirt for 235 days without difficulty.

I could go on to asbestos, which, because of a 1 in 10 million risk, we're spending, or we're scheduled to spend between $53 billion and $150 billion; zinc standards; the list goes on and on.

I don't think there's a Member here who fails to know about the scope of this problem. And believe me, across America, not just in corporate America but in your cities and towns, people are rising

up. Somebody was in my office last week from the town of New Iberia and they have some new regulation out that says that—the present regulation says you can have 30 parts per billion of arsenic, and they are proposing to bring that down to between 2 and 5 parts per billion.

And this engineer who represents New Iberia says they can't achieve the 2 parts per billion, and the 5 parts per billion would cost millions of dollars and would be the equivalent of, if you drank four glasses of water a day for 5 years, it would be the equivalent of the amount of arsenic you get in a plate of shrimp.

Now, how many of you know these kinds of examples? Now, why can't we do anything about it? Do we recognize the problem? Does EPA dispute this? No. No, as a matter of fact, EPA, in 1987, published a document called "Unfinished Business," where they found that there was little correlation between risks that the EPA staff judged as most threatening and the EPA program priorities. They found that, "Overall, EPA's priorities appear more closely aligned with public opinion than with our estimated risk." That's EPA that said that about its own risks.

In 1990 they published another tome on "Reducing Risk." Same conclusion.

Look at what OMB says. They have a regulatory program of the U.S. Government that they published for April 1, 1992 through March 31, 1993, where they talk about risks and the costs, and you've got some risks which—for example, here's the hazardous waste listing for wood-preserving chemicals, which saves one life for every $5.7 trillion.

Here's one for Atrazine Alachlor Drinking Water Standard, which, according to them, saves one life for every $92.069 billion. I mean, the list varies wildly and is an indication of the lack of any systematic application of a risk standard, any understanding of what they're doing. And friends, this is not beanbag; this is serious dollars.

And it seriously affects the competitiveness of this country. It seriously affects the job base in this country, and it seriously affects what your constituents and mine have to pay for doing business with the U.S. Government.

Now, what does this amendment of mine do? First of all, it says the Administrator shall file a certificate which shall first state what the cost of a proposed regulation is. Second, it states that the benefits justify the cost, not that they equal the cost but that, in the opinion of the Administrator, that they justify the cost.

We're not trying to state that there is a standard where a life is worth so much and you've got to measure it against—that's not what the amendment says. It says you must state that it justifies the cost.

Third, that it's based upon the best available scientific data. Why that? Because sometimes they choose to ignore the best scientific value. That carbon 14 regulation I was telling you about was adopted in absolute contrary opposition to what the scientists had said, but they wanted to adopt it anyway. But we require that it state that it's based on the best scientific data and that you compare it to other risks that people are ordinarily exposed to.

For example, on the arsenic, compare it to a plate of shrimp or, on the carbon 14, compare it to the amount in the body naturally. It's up to the Administrator what to compare it to.

Now, what's the purpose of this certificate? If it's not to be the stuff of a lawsuit, what's the reason for it? Well, two reasons, really. First of all, in a desire to get a rigorous culture of science throughout EPA, we want EPA to look at—I mean, EPA should never adopt a regulation without some idea what the cost is. And surely they shouldn't adopt one that's not based on the best science.

And to compare it to other risks which occur naturally, I mean, the Administrator or the Secretary can choose what those examples are, but it is meant to give the public a little education.

The Administrator is free to ignore her own certificate. Or indeed, if she fails to provide the certificate, or does it wrong, or if she adds up the figures incorrectly, or if she intentionally makes a wrong certificate, it is not to be the basis of a cause of action or a lawsuit.

That's not what we're after. We want the Administrator and her staff, in her own head, to go through the intellectual discipline, the logical discipline which risk assessment entails. That's what we're after here, is to go through that, and then, once it's gone through, then to give it out in understandable form to the public. We want the public to understand, because the public is going to pay for these regulations.

Now, will there be times when they can't accurately assess the risk or the cost? Sure. Will there be times when the public calls for more regulation than science provides for? Of course. That's what this democracy is about. But at least in the first instance, get the information out there to the public. Well, even before you get it out to the public, at least go through the discipline that gets you there.

I mean, don't adopt one of these regulations without being able to identify the risk. And sometimes they do that. They just don't identify the risk.

Now, it is perfectly clear that this changes no substantive law. It changes no power of the regulator. All the environmental laws will still be in place and it's not our intention to change those.

Now, what's it going to cost? Well, CBO said $20 million a year, or nothing if you apply it just to major rules, and that was before—CBO said that before they came out with their own set of regulations. And I submit their own set of regulations, they have to do a lot of this anyway.

Now, let's talk about this Executive order, because you know it's interesting. We're told, on the one hand, Bennett, we don't want your amendment because it's going to slow this thing down; it's going to cost too much money; but, by the way, we've already done it anyway in the Executive order.

Well, they have done something in the Executive order, but I would invite you all to read this Executive order. It is a masterpiece of words. I mean, look at this thing. It's as long as I don't know what, and it amounts to very little.

Listen to this, for example. You've got three big sections here. The first involves principles. It says that these 12 principles should be adhered to, should. You don't have to be a very good lawyer to

know the difference between "should" and "shall." So you should adhere to 12 principles, and then you read the principles, and then the principles say you "shall" use risk assessment. You should adhere to the principle of "shall" use risk assessment.

Now, either that is a monument to bad legal drafting or it is an intention to make it appear that there is something here that ain't there. And I can tell you, it is not there.

Second, it provides for a regulatory plan that applies to the most important significant regulatory actions. "Significant regulations actions" are defined as being regulations that involve $100 million or more, but "most more important significant regulatory actions" are not defined, so it means that the Administrator shall come up with an annual report dealing with some concept which she is free to define.

The guts of the Executive order are contained in section 6, which says that you shall assess benefits and costs. But section 6, which is the real guts, that requires what you do with your regulations, does not require risk analysis, does not require that it be based on the best scientific information, does not require that it be compared to other risks, does not require that there be a justification between the cost expended and the risk identified, does not, in fact, even require the identification of the risk.

So that in these marvelously complicated regulations, you end up with a requirement of very little. And, most important, they are free to exempt classes of regulations or individual regulations. In other words, it is consensual. It gives you, in effect, nothing more than you had before. Let me just sum up, Mr. Chairman. You've been generous with your time.

Mr. CONYERS [presiding]. I always am, when a Senator is in the room.

Mr. JOHNSTON. By saying that to have an understandable certificate, which both the Administrator or the Secretary can understand and that the public can understand cannot do any harm to this regulatory system or to the Government of the United States.

And I would urge that this committee and the House of Representatives face up to one of the most serious problems facing America today, and that is the huge cost of regulation. Thank you, Mr. Chairman.

[The prepared statement of Mr. Johnston can be found in the appendix.]

Mr. CONYERS. Well, you're very welcome. And your ability and concern and persuasiveness has been felt by all of us here and the depth of feeling that you have about the subject matter.

Before we start with Ms. Katzen, I've noticed that the gentleman from California, Mr. Waxman, has entered the room. He's been conducting hearings elsewhere, and I wanted to recognize him momentarily.

Mr. WAXMAN. Thank you very much, Mr. Chairman. Senator and Ms. Katzen, we're pleased to see you here today.

The chairman and I have been taking turns because I chaired a hearing when he was a witness and I dismissed him out of order, and now he's doing me the favor of getting a chance to say a few words, but then I have to return to my own hearing.

I just wanted to commend the chairman for holding today's hearing. I think the testimony we'll receive on this whole question of risk assessment will debunk much of the myth about the use of risk analysis at EPA.

The fact is that EPA already uses risk analysis in their decision-making, but such analysis is not a panacea and is not relied upon as the exclusive basis for decisions, and that's as it should be. Those who seek to impose additional risk-based requirements as part of the EPA Cabinet bill are, in my view, misguided.

Risk analysis cannot address the fundamental policy questions that must be resolved in regulatory decisions—questions such as who do we protect? Everyone or the most sensitive individuals? How do we value a human life? How do we prioritize between preventing lung cancer, protecting children from lead poisoning, or protecting wilderness areas? What exposures do we assume? The exposure to an average person or the exposure to the most sensitive?

Greater use of risk analysis will be of help in efforts to address these critical matters, but risk analysis is simply one of the tools that can help us identify unmet environmental priorities. For example, the Surgeon General has found that 50,000 Americans die of cancer and heart disease each year from exposure to environmental tobacco smoke. This is a priority, based on any evaluation of risk that we ought to be addressing.

But mandating risk analysis will not succeed in improving EPA decisions or in reducing the cost of protecting the public health or the environment. We ought to have it as a tool when it's appropriate, and not in every case looked at as the sole answer. There's risk assessment, there's cost-benefit analysis, there's risk management. These are all important tools, and we ought to recognize in a case-by-case situation, they ought to be used when appropriate.

I thank the chairman for recognizing me to make these comments and I look forward to following this hearing, although I won't be able to do it by being present throughout.

Mr. CONYERS. Well, we let everyone make an opening statement. Senator Johnston, I know your schedule is busy and if it suits you, we would invite you to stay or we can excuse you whenever you choose. We deeply appreciate your attendance here today.

Mr. JOHNSTON. I would be glad to follow the lead of the chair. If there are any questions that anyone would have, I'd be glad to answer those.

Mr. CONYERS. I was trying to head them off, in my own subtle way, because we have a couple of panels here that Mr. Synar has put together. And you've been very clear in your remarks, sir. And we thank you.

Mr. JOHNSTON. I hope that means you agree, Mr. Chairman.

Mr. CONYERS. It's taken me a lot further than I expected to come when I got up this morning. I'll tell you that. You're very good.

Mr. JOHNSTON. Thank you very much for being so patient.

Mr. CONYERS. Ms. Katzen, you're the one who has been patient this morning. From the Office of Management and Budget, OIRA, we welcome you. We've got your statement and we'd like you to begin.

STATEMENT OF SALLY KATZEN, ADMINISTRATOR, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC

Ms. KATZEN. Thank you very much, Mr. Chairman and members of the subcommittee. It has been very interesting sitting and listening to your very articulate statements.

I appreciate the opportunity to testify this morning on risk analysis. It is an issue that is very important to the administration and to OIRA in particular.

I did prepare written testimony and I would ask that it be incorporated in the record.

Mr. CONYERS. Without objection, so ordered.

Ms. KATZEN. Thank you. OIRA has specified statutory responsibilities and is charged under various Executive orders with coordinating and reviewing executive branch regulatory policy matters.

There have been several references this morning to the Executive order on regulatory planning and review which was signed by President Clinton on September 30, 1993. That order sets forth various principles and processes to promote a regulatory policy that is not proregulation or antiregulation, but designed to produce smart regulations—regulations that will limit pollution, increase worker safety, discourage unfair business practices, and contribute in a host of ways to a healthier, safer, more productive and equitable society, without imposing undue costs, retarding innovation, reducing productivity, or distorting incentives.

In the section on regulatory principles, the Executive order instructs agencies to identify the problem that they intend to address and to assess the significance of the problem. And while it is stated in terms of "should," when the President of the United States signs an Executive order, speaking to those who are Presidential appointees, the "should" carries great weight.

Of particular relevance, the order states that in setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risk posed by various substances or activities within its jurisdiction. In the section on planning, it says that Federal agencies are to consider how the action they propose will reduce risk to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action proposed relates to other risks within their jurisdiction.

The Executive order also emphasizes the importance of good data. It says each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and the consequences of, the intended regulation.

This brings us squarely to risk analysis, for it is one generally recognized mechanism to incorporate science into regulatory decisionmaking, and it is a means of organizing scientific, technical, social, economic information in a way that enables policymakers—not the scientists but policymakers—to understand the consequences of their actions and hence, make informed choices.

Finally, under the Executive order, my office is charged with reviewing significant executive branch regulations, including specifically the assessments and the analyses—including risk analyses—

that justify the proposed regulations, to ensure that the agencies have adhered to the Executive order.

Not surprisingly, I believe in analysis. I believe in cost-benefit analysis. I believe in risk analysis. The chairman this morning stated that there's nothing magic about risk analysis. There's nothing mysterious about it, either. At one level it is a very basic concept. We live every day with risk analysis. Life is full of risks, and risk analysis is a way of gathering, assembling, arraying the information that one needs to make decisions.

For example, you have a cold. You can take one of several medicines. Some are stronger, more effective. But those that are more effective may make you drowsy or have other adverse side effects while they're reducing the symptoms that you're complaining about.

Of course, you have the option of not doing anything. You might improve quickly. You might, however, develop sinusitis or something more serious. You consider all these factors before you take the action that you're going to take—to medicate yourself or otherwise.

Now, the concept is simple, and the implementation in this hypothetical is relatively straightforward. But when you look at implementation of risk analysis in the area of health, safety, and environmental regulations, it is quite complex and quite difficult, taking us to various levels of a variety of disciplines, including the natural sciences that we heard about today, and the social sciences. For example, exposure to a toxic ingredient is behavioral, in part. It involves economics, the costs that are involved in the various selected strategies, statistics, even psychology. Implementation of risk analysis is almost never as simple as choosing medicine for a cold.

Now, as the chairman said earlier, risk analysis is a tool. It is one of many tools in the regulatory tool kit.

Because it is so important and because it represents the convergence of science and regulation, Dr. John Gibbons, who is the Assistant to the President for Science and Technology in the Office of Science and Technology Policy [OSTP] in the White House, and I convened representatives of the White House policy offices and the regulatory agencies that regulate risk to discuss this issue.

The purpose of the meetings was to use the Executive order on regulatory planning and review as a point of departure and build consensus for a comprehensive, coherent approach to risk analysis across the agencies that address environmental, health, and safety issues. Our goal was to promote the development of consistent methodologies, where appropriate, and prevent gaps or duplications of effort.

What has emerged from these discussions is a basic framework that sets forth our approach to risk assessment, risk management, risk communications and the setting of priorities. The framework is set forth in my written testimony and I'd be happy to answer any questions on that material.

We want to move from this framework to a series of guidance memorandums beginning—probably within the next few weeks—with a very general statement of our basic approach, and then sub-

sequent memorandums, as necessary, addressing more specific issues of implementation.

The analogy that I use is peeling layers of an onion. We intend to approach this step by step—as an evolving process rather than a one-shot attempt to provide a definitive statement on an issue which simply does not lend itself to that.

Our efforts are going to be focussed through two particular activities. The President recently signed Executive Order 12881 establishing the National Science and Technology Council, and OSTP is currently organizing a subcommittee on risk that will look at the more technical, scientific aspects of risk assessment. It will include most of the Federal agencies that regulate health, safety, and environmental risks.

Second, under the Executive Order 12866, I chair a regulatory working group which consists of representatives of the major regulatory agencies and the White House policy offices. At our most recent meeting, a week ago, we created an interagency committee on risk analysis.

One of the projects that committee will undertake is a compilation of the statutes that, in some way, require regulation of risk. As Chairman Synar noted, to a certain extent, the priorities that are set forth have been set by Congress—the agencies are not able to change them.

Those statutes deal with risk in a variety of ways: some tolerate no risk; others speak of "reasonable," and still others use the term "not unreasonable" risk. There are references to "safe risk," and to "significant risk."

Some statutes preclude any consideration of costs in risk management, while others use such terms as "affordability" or "feasibility" or "cost effectiveness." We will look for ways to work with Congress to bring greater consistency to the process. If you want to make a difference, a real difference, I believe this is the path to pursue.

One of the other priorities of the committee of the regulatory working group is to evaluate the feasibility of looking at risks across agencies—commonly referred to as comparative risk analysis [CRA]. We have to consider the feasibility of such a venture because there are differences in available data, and differences in the depth of knowledge and the methods used to estimate risk that make the process extraordinarily difficult. Nonetheless, CRA warrants our attention and further consideration. And the members of this interagency group, who live with these organic statutes and who deal daily with the particular issues, are in the best position to handle it.

Now, I want to stress again that many agencies are engaged in regulatory risk. While risk analysis has most recently been discussed in the context of EPA, it is applicable across a broad range of agencies, including the Department of Energy and the Department of Defense, which must clean up contaminated sites; the Food and Drug Administration, which is charged with managing food safety and approving drug and medical devices; the Occupational Health and Safety Administration; the Consumer Product Safety Administration; the National Highway Traffic Safety Administration, and many others.

The principles of risk analysis apply to all of these agencies. The administration, therefore, believes that the subject should be addressed in a consistent and comprehensive manner, rather than by a piecemeal approach, program by program or agency by agency.

As you know, the President has said he would oppose the Johnston amendment because he wants a clean bill—one only relating to the structure, organization, or status of EPA. And while Jack Quinn had worked with Senator Johnston, we did not support the amendment because of our preference for a clean bill. But beyond process, there is the issue of the amendment's limited applicability to EPA and the real need for these rules to be applied consistently.

There's also a question of timing. We have learned a lot. The issue has been subject to enormous attention, and that is highly beneficial. But this is an evolving field, and to freeze in time where we are now, I think, would be counterproductive.

Part of our group's efforts will be to continue to retain sufficient flexibility so that we can learn and incorporate new thinking in the process. And it is important that we develop a broad-based concensus including not only the agencies, but also the Hill, and specifically with members of this committee, and with State and local governments, public interest groups, businesses, and the public at large. All have a stake in this.

[The prepared statement of Ms. Katzen follows:]

Statement of Sally Katzen
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
before the
Committee on Government Operations
Subcommittee on Environment, Energy and Natural Resources
Subcommittee on Legislation and National Security
United States House of Representatives

February 1, 1994

Introduction

Good morning Mr. Chairman and Members of the Subcommittees. I am the Administrator of the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget. OIRA has specified statutory responsibilities and is charged under various Executive Orders with the task of coordinating and reviewing Executive Branch regulatory policy matters.

I appreciate the opportunity to testify on the issue of risk analysis. It is an issue that is very important to the Administration, and to OIRA in particular.

The discussion of risk analysis is not new -- policy makers, scientists, economists, and students of public administration have debated various aspects of risk analysis for years. There is a substantial (and growing) body of literature on the subject, and over the last few years, risk analysis has received increasing attention and visibility and as a result is finally, in a sense, coming into its own. But despite the raised attention, there is still some confusion as to what risk analysis is all about, and certainly no agreement as to the role it should play in public policy decision-making, and specifically when, how, and by whom it should be used.

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The concept of risk analysis appears to be relatively straightforward and simple, although its implementation can be quite complex and challenging. As you know, life is full of risks and those engaged in public policy (elected and appointed officials in both the legislative and executive branches) are often called upon to act to reduce those risks or minimize their adverse effects. Risk analysis is a way of organizing what we know about risk. To reduce a particular risk, there may be several courses of action; each course may present its own risks, and there is obviously the risk of doing nothing. Consider, for example, the concern about injuries resulting from automobile accidents that was the subject of public policy debates several years ago. Risk analysis provides a method of estimating the frequency with which such injuries occur and the relative effectiveness of seat belts and/or air bags in reducing the injuries sustained; it also provides a mechanism for estimating the relative costs of the possible alternatives -- both the direct costs and the possible indirect costs (e.g., some drivers may drive even faster on the assumption that they can do so safely with passive restraints, thereby increasing the risk of injury to persons and property). Clearly risk analysis does not itself determine the outcome -- in this case, what protections should be mandated. The selection of the appropriate risk management strategy is for the public policy decision-makers, but risk analysis is a useful tool for assembling and arraying the information, so that those decision-makers can make more informed decisions.

The above discussion also should make clear that risk analysis may be useful for a broad range of risks. Recently, the subject has been discussed primarily in the context of the work done by the Environmental Protection Agency. Yet, risk analysis applies to all agencies with missions to reduce hazards to human health, safety or the environment, including the Department of Energy and the Department of Defense, which must clean up contaminated

sites; the Food and Drug Administration, charged with managing food safety and approving drug and medical devices; the Occupational Safety and Health Administration, the Consumer Product and Safety Administration, the National Highway Traffic and Safety Administration and many others.

Given the importance and the cross-cutting nature of the issue, the Executive Office of the President has sought to provide leadership in this area. I'll be focusing in this testimony on activities in which the White House is specifically involved. There are, however, many important activities at the various agencies. You will be hearing later this morning from Lynn Goldman, the Assistant Administrator at the Environmental Protection Agency and the Director of its Office of Prevention, Pesticides, and Toxic Substances, who will be providing information about some of the fine work EPA is doing in this field.

Background

The Clinton Administration is committed to a sound, effective regulatory policy, and it recognizes the importance of risk analysis in the regulatory decision-making process. The Executive Order on Regulatory Planning and Review (E.O. 12866), signed by the President on September 30, 1993, seeks to establish a regulatory policy that "works for [the American people], not against them." It sets forth principles and processes to promote a regulatory policy that is not pro-regulation or anti-regulation but smart regulation -- regulation that limits pollution, increases worker safety, discourages unfair business practices, and contributes in many other ways to a safer, healthier, more productive and equitable society, without creating undue burden, retarding innovation, reducing productivity, distorting incentives or adversely affecting living standards.

In the section on regulatory principles, the Executive Order begins by requiring agencies to identify the problem that they intend to address as well as assess the significance of that problem. (Section 1(b)(1)) Of particular relevance here, the Order states that Federal agencies are to consider "how the action [they propose] will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency." (Section 1(b)(4)) In the section on planning, the Executive Order states that "in setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risk posed by various substances or activities within its jurisdiction." (Section 4(c)(1)(d))

The Executive Order also emphasizes the importance of good data: "each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation." (Section 1(b)(7)) Risk analysis thus is only one tool -- but a very important tool -- in the regulatory tool kit; it is a mechanism to incorporate science into regulatory decision-making and a means for organizing scientific, technical, social and economic information in a way that enables policy makers to make informed choices.

Given the convergence of science and regulatory policy, Dr. John H. Gibbons, Assistant to the President for Science and Technology and the Director of the Office of Science and Technology Policy (OSTP), and I convened representatives of the White House policy offices and the regulatory agencies that regulate risk to discuss this issue. The purpose of the meetings was to build consensus for a comprehensive and consistent approach to risk across agencies that address environmental, health and safety issues; our goal is to promote the development of consistent

methodologies, where appropriate, and preventing gaps and/or duplication of efforts across agencies.

Our initiative was well received, and after several meetings we developed a basic framework, a preliminary structure of principles of risk analysis. Our approach can be divided into four areas:

Risk Assessment. The first step in risk analysis is to assemble some of the relevant data. Risk assessment is the term used for the process of describing or characterizing the nature and magnitude of the risk. It includes, for example, a measure (whether it be a point or a range) both of the toxicity of the substance and the anticipated exposures. Characterization of risk should be both qualitative and quantitative (i.e., both descriptive and mathematical).

Risk assessment -- even when it employs the best available evidence -- is not an exact or perfect science. There are many questions and uncertainties associated with the risk analysis process. Indeed, the literature is filled with debates on such technical issues as whether to extrapolate from lab animals to humans on the basis of body weight or surface area.

In addition, science does not have all of the answers; there are and will inevitably be -- no matter how much we learn -- gaps in scientific knowledge. It is essential, therefore, that when judgements and inferences are made to bridge these gaps, as they necessarily will be, they should be made explicit. There will also inevitably be uncertainties even about "scientific facts". Not only must risk managers be informed about the existence (and magnitude) of the uncertainties that exist, they must also be informed when such factors as "conservative assumptions," "margins of safety," and "uncertainty factors" are incorporated in the analysis.

It is also important to separate the inferences grounded in the natural sciences, as well as the economic, technical, and behavioral sciences, from policy judgements (see "Risk Management" below). The former (the set of facts and inferences grounded in the sciences) should pass muster under peer review by those in the same discipline, who should have an opportunity for such review to ensure that the underlying work was done competently and that any assumptions made are reasonable. Public comment would also help to ensure that the highest professional standards are maintained.

Risk Management. Risk management is the process of weighing risk estimates with or against other key elements of public policy decisions, such as equity, quality of life, individual preferences, cost-effectiveness, and the distribution of costs and benefits. In other words, risk management is the process by which risk assessment data are augmented by analyses of other benefits (both direct and indirect, both quantifiable and non-quantifiable) associated with the selection or implementation of a risk management strategy, together with analyses of the costs (both direct and indirect, both quantifiable and non-quantifiable) associated with each strategy. These are the decisions that should be made by the elected and appointed officials charged with the responsibility (and accountable to the public) for public policy.

It is essential that those in public policy charged with risk management keep open the lines of communication with risk assessors to assure that risk assessments anticipate and address the widest range of risk-related issues that will be relevant to the risk management decision. It is also essential for the risk managers to keep open the lines of communication with the public so that their perceptions can be incorporated into the decision-making process.

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Risk Communication. The exchange of information about risks, and perceptions about risks, between the policy makers and the public is known as risk communication. When "experts" describe the risk, it is important to explain the basis for significant assumptions, data, models, and inferences used or relied upon; and to describe the extent and magnitude of significant uncertainties associated with the assessment or decision. Not only should risks be communicated accurately and objectively, but they should be communicated in a way that can be readily understood by the public in the context of other familiar risks.

The importance of communicating risks to the public is underscored by some studies that demonstrate little correlation between public perception and scientific judgements about the magnitudes of risks for a number of activities. Some have suggested that this is a function of media attention on certain risks that are more easily understood (and hence covered by the mass media) to the detriment of coverage of potentially more harmful, but more complicated, risks. Indeed, other studies show that when the public is provided with the relevant information in an understandable manner, their choices more closely parallel those of the "experts".

There are other possible explanations for the apparent divergence between "expert" and public perceptions. One is that the public's ranking of risks may reflect the incorporation of other or different values from those used by the "experts". For example, while it is widely accepted (and well publicized) that, on average, driving an automobile is more dangerous than flying some distance, many people choose to drive instead of fly because of an acute fear of air travel. Another explanation for the discrepancy may be the distinction between voluntary and involuntary risks. It may be that the public will react more adversely to the involuntary (if it is truly involuntary) risk of living next to a nuclear power plant (which has a relatively

small health risk) than to the voluntary risk of smoking several packs of cigarettes a day (which is a well-documented high health risk). There is also the effect that the distribution of benefits may have; in the preceding example, most smokers say they enjoy smoking, whereas residents living next door to a power plant may not derive any benefit from their proximity to the site. In any event, given the different perspectives, it is important that risk communication truly be a two-way process.

The Setting of Priorities. Risk analysis provides an important input for the setting of priorities. It helps us allocate limited resources so they will have maximal impact -- in other words, so we can achieve the "biggest bang for the buck".

Accordingly, we believe that agencies should rank risks within their jurisdictions. When it is not feasible to do so with precision, the relevant decision-makers should attempt to group them in broad risk categories (e.g., high risk, moderate risk, and low risk.

As with risk management decisions, the setting of priorities should take into account the views of internal agency experts and a broad range of individuals in state and local governments, industry, academia and non-governmental organizations, as well as the public at large. Where possible, the relevant decision-makers (and again, these are the elected and appointed policy officers) should attempt to reflect consensus views in the setting of priorities and should attempt to coordinate risk reduction efforts wherever feasible.

Major Short-term Administration Objectives

Our intention is to continue the dialogue we began with the agencies and ultimately to produce a series of guidance memoranda

beginning with a general statement of our basic approach and then subsequent memoranda as necessary addressing more specific issues of implementation. Like peeling layers of an onion, we intend to approach this issue step by step; we envision an evolving process, rather than a one-shot attempt to provide the Administration's definitive statement. We have chosen this course not only because of the number and complexity of risk analysis issues, but also because we perceive a need to develop a broad-based consensus, not only within the Executive Branch, but with those on Capitol Hill, State and local governments, business groups, and public interest and non-governmental groups. All of these stakeholders are affected and all can contribute to the process. Furthermore, risk analysis is an evolving process and we must retain sufficient flexibility to incorporate advances in thinking about the subject.

As we continue our work, our efforts will be focused through two particular activities on risk that are centered in the White House and that will be proceeding in parallel. First, the President recently signed Executive Order 12881 establishing the National Science and Technology Council (NSTC). Currently, OSTP is organizing an NSTC Subcommittee on Risk Assessment to evaluate the risk assessment aspects of risk analysis. This Subcommittee will examine the scientific issues associated with the evaluation of risk, including issues pertaining to cancer, noncancer, and ecological risk assessment methodologies in general. The Subcommittee will include most Federal agencies that regulate health, safety and environmental risks.

Second, under E.O. 12866, the Administrator of OIRA chairs a Regulatory Working Group (RWG) consisting of representatives of the major regulatory agencies, the White House policy offices, and the Office of the Vice President. The Order charges the RWG with exploring the methods, efficacy and utility of comparative risk assessment. At the most recent meeting, we established a

committee on risk analysis to be co-chaired by OSTP and EPA. One of the projects the committee will undertake is the compilation of statutes that in some way require regulation of risk. As you know, the manner in which statutes deal with risks varies widely -- some tolerate no risk, while others speak of "reasonable" or "not unreasonable" risk or "safe" or "significant" risk; some statutes preclude consideration of costs in risk management, while others use terms such as "affordability" or "feasibility" or "cost effectiveness". We will look for ways to work with the Congress to bring greater consistency to the process. The RWG committee will also explore the feasibility of comparing risks across agencies. We recognize that differences in available data, depth of knowledge, and the methods used to estimate risks make comparative risk analysis difficult. However, while it may be rough and inexact, the committee is charged with exploring whether such an undertaking would be useful.

In addition to these two parallel tracks, the Administration is also in discussions with various non-governmental organizations to participate in, be aware of, and promote risk-related projects. For example, we are working with Resources for the Future on issues related to managing risk and setting priorities. Through the Keystone Center, we hope to initiate a policy dialogue on risk analysis, a broad-based discussion on how risk is evaluated and used in making regulatory decisions. We recently participated in the Interbranch Forum on Risk at the Brookings Institution, a discussion of risk policy among the executive, legislative and judicial branches of government. And we are having discussions with the National Research Council about a potential study on the scientific aspects of risk based priority setting.

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Conclusion

Risk analysis is an undeniably important part of regulatory decision-making because of its usefulness as a tool, albeit an imperfect one, for setting priorities and for selecting among alternative courses of action. The Administration has made significant progress in this area, through Executive Order No. 12866 and with our interagency consultations. Because the principles of risk analysis are applicable across agencies that regulate risks to health, safety and the environment, it is important that we develop a broad-based consensus. It is also important that we consult extensively with other interested entities, including the Congress (and specifically the Members of this Committee), State and local government officials, and representatives from businesses, public interest groups, and the public at large. I look forward to continuing our work with your help.

This concludes my prepared testimony. I look forward to answering any questions you may have.

Mr. CONYERS. Thank you so much, Ms. Katzen. We're off to a good start. The ranking member, Mr. McCandless from California, is recognized.

Mr. MCCANDLESS. Thank you, Mr. Chairman.

Ms. Katzen, I wondered if you would—I'm sure you have a copy of Executive Order 12866 there in one of your piles?

Ms. KATZEN. Actually, I don't, but I'm very familiar with its terms.

Mr. MCCANDLESS. Well, there seems to be a need for an amplification of your comments relative to those of the good Senator. On page 2, subsection B, it says, "The principles of regulation." And then it goes on to say, "to ensure that the agency's regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable."

Then it goes ahead to say, "Each agency shall identify," "Each agency shall examine," "Each agency shall identify and assess." But key here, unless I'm missing a point somewhere, is the principles of regulation should adhere to the following.

Ms. KATZEN. I believe that the language is "to ensure that they are consistent with the President's program and priorities, agencies should do this." It's a normative statement. It provides a means to an end, such as: to get from here to there, you "should" turn left at the stoplight.

Mr. MCCANDLESS. Why don't we send this down to you and have you comment on it, because not being an English major, maybe I'm misinterpreting the language here. Page 2.

Ms. KATZEN. Judge Breyer has one. Yes?

Mr. MCCANDLESS. Or maybe we can get a judicial opinion on this.

Ms. KATZEN. Sir, it may have been inartfully drafted, and I will accept some responsibility for that, but the statement is that to ensure that the agencies are consistent with the philosophy, they should do the following: A, B, C, D, and E. As I said earlier, it's a normative statement of how an agency gets from here to there. While we may not have written it perfectly, the agencies understand that they are obligated to adhere to the principles. I do not think there is any dispute about that.

Mr. MCCANDLESS. Then it's your conclusion or interpretation that, in essence, the rest of the following 1 through 12 are "shalls" and "shall be done by the agency."

Ms. KATZEN. Yes. And if the "shalls" are done, the programs would be consistent with the philosophy set forth in the order.

Mr. MCCANDLESS. Thank you, Mr. Chairman.

Mr. CONYERS. You're welcome. Chairman Synar.

Mr. SYNAR. Thank you, Mr. Chairman.

Ms. Katzen, let's start off with this. Is this problem unique to EPA or is this across the government?

Ms. KATZEN. No, it is across the board, from the smaller agencies that are specifically assigned tasks, such as OSHA and FDA, to those that you wouldn't think——

Mr. SYNAR. So the Johnston amendment only applies to EPA, correct?

Ms. KATZEN. It does indeed.

Mr. SYNAR. All right. Now, when you took over office a year ago, how backlogged were you at OIRA, with respect to regulations? How many were on hold?

Ms. KATZEN. I don't have the specific numbers. The President issued a memorandum his second day in office asking that those regulations that were on hold be returned to the agencies to be reviewed by a Clinton appointee.

Mr. SYNAR. What's our status now, given the Executive order and the 90-day review rule?

Ms. KATZEN. I saw some data recently which showed that the numbers are declining and the time line is declining, as well, as we urge selectivity. This is a point which we grappled with in drafting the Executive order. Should we look at all regulations or be selective?

Mr. SYNAR. Well, I'm going to get into that in a second. Now, the Johnston amendment basically requires a review of every single EPA regulation. How many of the EPA regulations are what are called routine or not costly or controversial?

Ms. KATZEN. There was a study done several years ago that showed that close to 50 percent were relatively routine.

Mr. SYNAR. So implementing the Johnston amendment would literally cause paralysis by analysis wouldn't it?

Ms. KATZEN. Yes.

Mr. SYNAR. Now, one of the things that concerns me about the Johnston amendment is that it really flies in the face of what we've been trying to do with what we called risk "assumptions." Many argue that we've got to get away from that and we've got to get into what's called good data to make these decisions. Many of my colleagues have commented on that today.

Am I wrong in concluding that if we want to base more of these decisions on data, rather than on assumptions, that we're going to have one hell of a paper chase through corporations, through industries that are going to have to provide that "good data" to EPA and that we are going to overburden them more than they ever anticipated, by requiring more data from them to make what's called "good data" decisions.

Ms. KATZEN. It depends on how comprehensive you have to be. If you're going to require risk analysis for the routine matters, it would, I think, cause paralysis, which is why I answered "yes" to your earlier question.

Mr. SYNAR. But there's a potential that industry and particular companies and others are going to have to provide more information under the Johnston amendment, versus less.

Ms. KATZEN. It's hard to answer that categorically because there are different program offices, which have different data already available. Some offices are data rich and some are data poor.

Our hope would be to get good, quality data throughout. Some of that could be generated by the agencies, not by the businesses, but others would have to come from those who have it.

Mr. SYNAR. All right. One final question. We're going to hear from Judge Breyer in the next panel. His comment is that "The people who are currently performing risk assessment and risk management duties lack sufficient multidisciplinary expertise to

make these scientific, economic and policy decisions." I think that's a direct quote from his testimony.

Do you believe that's true for your staff?

Ms. KATZEN. I'm not sure which people he's talking about. If he's talking about my staff, I have multiple disciplines represented within the staff. Of course, risk management is undertaken by the policy people rather than scientists. Our office checks to see that they have been provided with the information so they can make the policy judgment.

Mr. SYNAR. But the reviewers themselves don't have that scientific, multidiscipline ability.

Ms. KATZEN. In my office or the EPA?

Mr. SYNAR. In your office.

Ms. KATZEN. My staff is primarily strong in public policy—in economics, statistics, engineering, and some sciences—but we use the Office of Science and Technology Policy [OSTP] within the White House for scientific support, and the Council of Economic Advisors [CEA], for economic support there. In this way we bring the multiple dimensions to play.

Mr. SYNAR. Thank you.

Mr. CONYERS. Thank you, Chairman Synar. The chair is pleased to recognize the gentleman from Florida, Mr. Mica.

Mr. MICA. Thank you, Mr. Chairman.

How often, Ma'am, do we have an opportunity to create a Cabinet-level position? Are you aware?

Ms. KATZEN. There have been three or four since I came to Washington, but it's not a daily event, thankfully.

Mr. MICA. What's the difference between an Executive order and a law?

Ms. KATZEN. An Executive order can more easily be modified to reflect changes in thinking and the development of ideas than legislation, which, once passed, often remains on the books, whether it's timely or not, whether it's responsive or not.

This is one of the reasons why cost-benefit analysis and risk assessment have been the subject of Executive orders, rather than legislation, since President Nixon. With every President since Nixon, this subject has been handled by Executive order. President Carter, President Reagan, President Bush all issued Executive orders to set forth the provisions that they wanted to see applied in the review of regulations.

Mr. MICA. Which has precedent, the law or——

Ms. KATZEN. The law does, and for that reason, there are times when our office will call for more cost information and we are told that the Agency's statute precludes it from considering it. We, of course, must defer to the law.

Mr. MICA. So actually, we have a problem with the law that an Executive order cannot address. Is that correct?

Ms. KATZEN. We only have a problem where the law precludes or limits or restrains in some way the type of analysis that our agency may consider. But if the law is silent, then the Executive order fills the gap by calling for the analysis and data.

Our Executive order cannot, of course, apply to congressional decisions. But then legislation would not be covered by the provisions of the proposed amendments to the EPA elevation bill.

Mr. MICA. One of the problems that we have is that Congress has indeed passed all of these laws and set priorities that, in fact, may or may not be conflicting. And my concern is we just heard Senator Johnston say that we'll probably be worse off with the Executive order or we'll be in the same position we are, and it's meaningless.

Ms. KATZEN. I have great respect for the Senator but I do disagree with him on that subject.

Mr. MICA. What's the difference between "shall" and "will"?

Ms. KATZEN. The difference between "shall" and "should" is that "shall" is binding; "should" is not. But, when they're both spoken by the President of the United States, speaking to those whom he has appointed, there is little, if any, difference. When the President tells me that I should be doing something, I certainly think I will do it.

Mr. MICA. Well, what's interesting is, and I'd love to have you come to some of the hearings we've had just in my short tenure of the Congress, but no one seems to be listening. And that's probably echoed by the sentiment of every public body I can think of, from the Governors down to the lowest elected official at the local level; business, industry, and agriculture are totally frustrated with the process, and they aren't listening.

We've heard testimony that the bureaucrats do not listen, and we have an opportunity here to do something that, in fact, would be directed in law rather than in an Executive order without teeth.

Ms. KATZEN. Well, with respect, I was confirmed in late May, and since then I have met with several agencies, not just EPA, and a number of bureaucrats. It is very clear to me that they hear me, and that they are aware of the Executive order and are responsive. There is a very significant dialog that is taking place and from which we are all benefiting, but you have to give the Executive order a chance to work. We have in place, I believe, a very solid basis for proceeding.

Mr. MICA. Fortunately, bureaucrats and Members of Congress are only temporary fixtures and we do live under a system of government that is provided for by law.

I have additional questions of a technical nature, based on some of the points in the Executive order, and I won't belabor the time of the committee with that, but I ask unanimous consent that I submit them to the witness for response at a later date.

Mr. CONYERS. We would like to have them submitted and the answer included in our hearing.

Mr. MICA. Thank you, Mr. Chairman.

[The material can be found in the appendix.]

Mr. CONYERS. You're welcome. Mr. Gary Condit, the man who we promised these hearings to.

Mr. CONDIT. Thank you, Mr. Chairman. I appreciate that very much.

Ms. Katzen, thank you very much for being here today and thanks for your help in this issue. You've been very informative and very helpful and I personally appreciate that.

I would like to ask, would the administration be opposed to legislation proposed to codify or comply with the intent of the Executive order on regulatory planning and review?

Ms. KATZEN. It's hard to commit in advance, before seeing the actual language. As I stated earlier, I believe deeply in the provisions in the Executive order, and I think that it sets forth good policy. I also believe those provisions belong in Executive order, so that they can be modified, if necessary, to make the order tighter or looser.

When the President signed the Executive order, he issued an accompanying memorandum calling for a report from my office, after the first 6 months, to evaluate how well it's working. I think that's the right approach. You drafted an order that received very strong support when it was issued, both by the business community and the public interest community. Most said, however, that the true test will be how it is implemented.

I will be delivering the 6 month report to the President this spring, and at that point we'll see whether there are adjustments that should be made. Once you put it in legislation, it's cast in concrete, and I think that's a problem.

But the order does apply across all agencies, unlike the Johnston amendment, and I think it's highly preferable in that respect.

Mr. CONDIT. I do appreciate the fact that you and other people in the EPA and other bureaucracies would like to have as much flexibility as possible, and I understand that is an objective. But those of us sitting up here may not want you to have as much flexibility as you want.

Do you concede to me that that's a legitimate concern?

Ms. KATZEN. I understand your position.

Mr. CONDIT. OK. Tell me, how does the OMB plan to deal with the issue of possible bias by agency in the implementation of its Executive order?

Ms. KATZEN. Possible bias?

Mr. CONDIT. Correct, the self-fulfilling prophesy that I mentioned earlier in my opening statement, that you justify the risks—that it's all inside baseball. It's the fox guarding the henhouse kind of approach.

Ms. KATZEN. Well, my experience in talking with the agencies about the issues that come before us, has been a very open, receptive, understanding discussion. When we're talking to the agencies, including the EPA, they're fully aware of the wide range of views on the subject.

I haven't seen the kind of bias that your question assumes, so it's difficult for me to say how I would deal with it. But what I do continue to preach the gospel, and talk to the various agencies, as each occasion arises, about the importance of analysis to inform decisionmaking, not to justify it, after the fact. This strikes a very responsive chord at the agencies. And certainly the political appointees, who are ultimately responsible to the President and to the electorate for their decisions, know they need the information, and they're pressing their staff to develop it.

So I think we're all speaking from the same script.

Mr. CONDIT. Well, it seems to me, though, when you really get into the gear of doing risk assessment, you begin to make decisions that either side who disagrees with that decision is going to challenge the process, and it seems to me you need to have an objective

way of evaluating that so that the numbers are fair, and whatever side criticizes, you say, "No, this is a legit, fair decision."

Ms. KATZEN. That's a very good point. I think, in that case, the answer lies largely in the transparency of the decisionmaking process.

In my written testimony I state that when one is talking about risk assessment, it is imperative that judgments, inferences, or assumptions be stated explicitly. If you're going to use a margin of safety, if you're going to use conservative assumptions, you ought to state explicitly what they are so that the policymaker, and ultimately the public, will be fully aware of it.

There was a call earlier in one of the opening statements for peer review. We support peer review to ensure that the highest professional standards are maintained. And again, in my written testimony, I walk through the various pieces of the process. I believe, the response to your concerns, which are very legitimate, is to make those kinds of judgments, inferences, and assumptions explicit.

Mr. CONDIT. Very good. Section 4 of the Executive order states that "Early in each year's planning cycle, the Vice President shall convene a meeting of the advisors and the heads of agencies to seek a common understanding and coordinate regulatory efforts."

Has this occurred this year, and will the results of the meeting be made public?

Ms. KATZEN. I believe we are trying for a late February or early March date for the meeting. It's a scheduling question. The meeting itself would not be open, but I'm sure that the results will ultimately be made public.

Mr. CONDIT. Well, I would encourage, for the question I asked right before this, that we have as much openness as we can because whatever decisions come out, you'll be challenged from the other side.

I do appreciate your being here this morning. Thank you, Mr. Chairman.

Mr. CONYERS. Thank you, Mr. Condit. The gentleman from New York, Mr. McHugh.

Mr. MCHUGH. Thank you, Mr. Chairman.

Ms. Katzen, welcome. A couple of questions on some of the comments you made, for my own edification. You said that exposure to a toxic substance is behavioral, in part. Am I correct in assuming you mean such as smoking cigarettes, those kinds of things? Or what other circumstances were you speaking about?

Ms. KATZEN. Well, there's also the results of risk communication. If you know it's a toxic and you can avoid it, then there's one way of having less exposure. If, for example, you're measuring exposure by breathing fumes, there is the question of whether it's voluntary or involuntary.

Mr. MCHUGH. Breathing——

Ms. KATZEN. Breathing fumes or breathing particles in the air.

Mr. MCHUGH. Voluntary breathing?

Ms. KATZEN. Breathing certain substances can be voluntary in some cases. If you're not a smoker and you're in a building and smoking is not prohibited, you may be inhaling second hand smoke. That might be involuntary, in that circumstance. On the other

hand, if a room is designated a "smoking room" with big signs, and you walk into the room, maybe because you want to smoke a cigarette, that may be voluntary in that circumstance.

That's one aspect of it. The other is that the degree of exposure that you have can, to some extent, be influenced by what you do and how you live your life, and if you know that there's a problem, and whether you nonetheless choose to be exposed.

Mr. MCHUGH. OK. Later, in defining risk, you talked of such things as reasonable risk and others. You said the phrase "safe risk." What is a "safe risk"?

Ms. KATZEN. There is a statute that required limits on exposure to a safe level, and then the agency would determine what a safe level is. It's a standard that is set in statutes. My point was simply that the statutes use a variety of terms, which then the agencies can or cannot interpret, depending on the extent of legislative history.

Mr. MCHUGH. So that would be interchangeable with, say, "acceptable risk"? Is that fair?

Ms. KATZEN. I would think so.

Mr. MCHUGH. These are not supposed to be complicated. I'm just trying to understand.

Ms. KATZEN. Well, I think part of the problem is that different terms are cast in different statutes. One statute uses "reasonable" another "not unreasonable." Are they the same? Are they different? What is the difference?

Our hope in compiling all the statutes, would be to come back to committees such as this and say, "Look at the differences. Look at the inconsistencies. Is this really what you want? Does this enhance our credibility? Does it enhance your credibility? Does the public better understand what we're doing if we're using different standards?"

It has happened that one agency will find that a particular substance is bad and will either eliminate it or restrict its use in some way, shape, or form, and another agency says it's acceptable. It's not because they're using different science in that instance. It's because they are governed by different organic statutes, which set different standards.

If you are implementing the Delaney clause that says "no risk" and you have another statute, one that says "acceptable risk," you could very well have such inconsistency. And that does not help any of us achieve what is optimal, in terms of good public policy or rational decisionmaking.

Mr. MCHUGH. You spoke of your 6-month report period coming up. Without trying to steal material from the President and Vice President's desk, how is it going?

Ms. KATZEN. The 6-month period isn't up yet, so I haven't yet begun to study what happened. My own sense is that it's going well.

Mr. MCHUGH. Could you share with me, as someone, as I mentioned in my opening statement, who has come in the relatively recent past from a different level of government and who has to deal with the more earthly impacts of these kinds of regulations, how the new process has helped local governments and businesses to deal with these issues?

For example, could you give me the past two or three changes in regulations that have been derived under this process that have saved localities money?

Ms. KATZEN. Well, one that is in process right now and, in fact, an EPA proposal is the result of a reg neg, a negotiated regulation in which stakeholders come to the table and themselves address how best to handle it. The Executive order also calls for more consensual-based regulation. The Executive order calls for more input by those who are expected to be burdened by, as well as those expected to be benefited by a proposed regulation. My understanding is that this particular EPA reg neg resulted in a much more cost-effective means of reaching the regulatory objective.

The President also signed another Executive order on October 26, 1993, called "Intergovernmental Partnership," in which the subject of unfunded mandates was specifically addressed. And on January 11 of this year, Leon Panetta, the Director of OMB, sent a memorandum to the heads of all agencies and departments transmitting guidance on how to implement that order. And that, I think, is a very important issue that the President is very concerned about.

Mr. MCHUGH. Which regulation was negotiated? I'm sorry, I didn't specifically hear.

Ms. KATZEN. This is one that EPA has not yet issued. It implements provisions of the Clean Water Act and has to do with combined sewer overflows, I believe.

Mr. MCHUGH. But that has not come about as yet.

Ms. KATZEN. It is currently being reviewed under the Executive order.

Mr. MCHUGH. Are there any that have been put into place, under your new system?

Ms. KATZEN. I can think offhand of a couple in different areas, other than the environmental area.

Mr. MCHUGH. But none in the environmental area?

Ms. KATZEN. Well, I'm trying to be very responsive to your question.

Mr. MCHUGH. I appreciate that.

Ms. KATZEN. I can get back to you.

Mr. MCHUGH. I'm not attempting to embarrass you. I'd certainly welcome a response if you could check through your files and if you could get back to us because I would seriously be interested in what positive on-the-ground working results have come about.

[The information can be found in the appendix.]

Mr. SYNAR [presiding]. The gentleman's time has expired. I've got to move on under the 5-minute rule.

Mr. MCHUGH. Thank you, Mr. Chairman.

Mr. SYNAR. Mrs. Thurman.

Mrs. THURMAN. Ms. Katzen, I have the very same question, so as you give that information of examples where the Executive order has worked, I'd be very interested in seeing it, not just in the environment, because quite honestly, to me, the whole issue should be across government. It's not just an environmental issue. Unfortunately or fortunately, the EPA bill was the first time we could get any recognition for this, and so therefore I think you saw a lot of us dumping on that to raise the issue in general.

However, I want to go back to something that the chairman said about every rule. Now, if I look at the testimony, or at least the record in the Senate of the debate that Mr. Johnston had in the Senate, it is my understanding, at least from his answers, that if they can't comply, they don't comply, and she just writes that. I mean, there is not necessarily every rule has to go through this. Is that correct?

Ms. KATZEN. Well, it covers all, and our concern is that it covers rules which are routine. When I first came to the Office of Information and Regulatory Affairs, one of the first regulations I saw was one proposed by the Department of Transportation, having to do with the time that you change the locks on the St. Lawrence Seaway.

This is a regulation. To do a cost-benefit analysis—the effect of going from eastern standard time to daylight savings time on the changing the locks and giving the public notice of that—does not make a whole lot of sense.

For that reason, we made the Executive order focus on "significant regulations." It's the comparison between the "significant regulations" that are the focus of the Executive order and the "all regulations" in the Johnston amendment that led us to be concerned about the overinclusiveness of the Johnston amendment.

Mrs. THURMAN. Ms. Katzen, however, I got the impression, from both the testimony and the letter written to the White House by Senator Johnston and others that there was the ability to communicate all of this, to sit down and talk about some of these issues, to where you might have some concerns.

I mean, I can understand the lock issue, but there are others out there that if they just seem to want to ignore them at this point, they can. I mean, I think all of us have looked at this issue as something where we're willing to work with you, but we're not, every time we get into this, we kind of end up in this fight kind of thing about why we should or should not put it into this legislation.

So I think that some of that could be looked at, and it certainly seems, from the testimony, or at least this Congressional Record in the Senate, that that was a part of it. Which leads me to the other thing.

I'm real concerned that when the administration sits down, with a Senator or a Congressperson, to work out language, and evidently, this bill or this amendment was taken off for a while, reworked and then come back, and now to come back and say that they don't support it, and yet, in fact, they support the idea.

The EPA Director, Carol Browner, sat in this committee saying that they approved of this and wanted these kinds of things. I mean, that was part of the testimony she gave to this committee.

I'm kind of concerned that we're saying one thing but not really doing what we had anticipated or what we thought was going to happen here. So maybe you can address that, because it's very alarming to me.

Ms. KATZEN. Well, I believe that there is a difference between being committed to certain principles and believing in certain objectives and the vehicle that you use to impose those or to require their adherence, and you, I think, yourself recognized on the

underinclusive part, when you said, "Well, it applies to other agencies; it shouldn't just be applicable to the EPA." This bill isn't the right vehicle.

This is a way, I believe, in which some members can say, "OK, I voted for risk assessment. I've done something." But to be perfectly honest, there are much more productive ways of really doing something, of being able to make a difference in this area. I am afraid this will give some people a chance of just saying, "Well, you know, I've voted for risk assessment," and then walk away.

Mrs. THURMAN. However, Ms. Katzen, when Mr. Condit asked the question specifically, could we do this, and would they accept the issue across the board, your answer was very hesitant. You said, "Well, we haven't looked at the language. We haven't done this."

He's asking to codify the Executive order into law. And so again, it seems like we're backpeddling. At one time you say the Executive order, and that's what we're looking at codifying, and then we turn around and backpeddle and say, "Well, you know, I don't know, unless we look at the language." It's your language. My time's up.

Mr. SYNAR. Mr. Clinger.

Mr. CLINGER. Thank you, Mr. Chairman. Just a comment and one question.

Thank you very much, Ms. Katzen, for coming up today and talking with us about this contentious but I think important issue that needs to have a full airing, and I think we're getting a pretty good view of where people are coming from.

The one comment I would make is that you indicated that one reason, or the primary reason for really opposing the Johnston amendment as part of the EPA operation was that you wanted a clean bill. I would therefore invite your attention to the substitute, which I will be offering tomorrow, which is truly a clean bill. It basically raises EPA to a Cabinet-level status, but does not have a number of things which I would consider not clean that are on the version that are going to be considered. So I would just——

Ms. KATZEN. I think the President's statement was that he would like this restricted to items relating to only the structure, the organization, and the status of EPA.

Mr. CLINGER. Right. Your phrase was "clean bill," and I'm just saying that "clean" is a relative term, and I would suggest that perhaps my substitute is a little cleaner than the one that we're going to have before us tomorrow.

The only question really is how did you arrive at the $100 million figure as the cut-point below which you would not consider or would not undertake risk? Was it an arbitrary figure?

Ms. KATZEN. The $100 million is one of the figures. The order also uses the criterion of adversely affecting the economy or a sector of the economy. You could have a $50 million industry, and if the adverse effects of the regulation totaled $48 million, it would clearly be significant.

So only one of them. But for nationwide, $100 million is, I believe, the figure that was used back in the early 1980's, either coming out of the Carter administration or the early days of the Reagan administration, to distinguish between a major or minor

rule. It is one that has served us well, and so we use that as one of the thresholds.

Mr. CLINGER. You're saying that it doesn't necessarily imply that it is an arbitrary cutoff, that you could, in fact, engage in risk analysis for a regulation that might have less of an impact, depending upon the industry?

Ms. KATZEN. That's right. The definition of "significant regulatory action" is one that has an annual effect on the economy of $100 million or more or adversely affects in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities.

There are a number of different ways in which significance is evaluated. I once said it was a little bit like the definition of pornography. It's very hard to define but you know it when you see it. A significant reg—you know it when you see it. And if you talk to the people who are working on a particular regulation, you say, "Is this significant?" most of the heads will shake in the same direction.

So we have not had a whole lot of disagreements about what is significant and what is not significant.

Mr. CLINGER. But the $100 million figure was really just a carryover as a factor?

Ms. KATZEN. It was a useful addition to our litany.

Mr. CLINGER. Thank you.

Mr. SYNAR. Mr. Zimmer.

Mr. ZIMMER. Thank you.

I appreciate your being here, Ms. Katzen. I'd like to have clarification on the position of the EPA on a risk assessment amendment. Is it your position that EPA should not be elevated to Cabinet status if there is a risk assessment amendment attached to the bill?

Ms. KATZEN. I'm not speaking for EPA. What I have said is that EPA should be elevated to Cabinet status. The President is very supportive of that, but he has also asked that the bill be restricted itself to those matters which pertain to the organization, the structure, the status of EPA, and that other matters, such as environmental policy be addressed separately. That is the position of the administration.

Mr. ZIMMER. So it is basically a question of process rather than the substance of the Johnston amendment that is the major factor behind the administration's opposition?

Ms. KATZEN. The elevation bill isn't the appropriate vehicle in which to address analysis. And so I guess that's an answer of "yes." I'm essentially a process person. I came to this job as an administrative lawyer, as someone involved in regulatory practice, someone who cares about good government and doing things the right way. That's why I care about analysis. That's why I care about rigorous exploration of the consequences of action.

It's the process part, and the amendment here does not serve that function.

Mr. ZIMMER. Well, could you interpret the position of the administration? It's been expressed in a number of ways. Will the Presi-

dent take out his veto pen that he showed us last week and veto the legislation if it has risk assessment language in it?

Ms. KATZEN. I cannot answer that question.

Mr. ZIMMER. If risk assessment legislation of the sort proposed by Senator Johnston or Mr. Condit, Mr. Mica and Mrs. Thurman came up on its own in some kind of appropriate process, what would your position be on it then?

Ms. KATZEN. I would very much like to look at the language, see what is required, work with the members of the committee, as appropriate. I can't give you the position of the administration on something I haven't seen. I'm sorry.

Mr. ZIMMER. Well, you've seen the Johnston amendment. You've seen the House counterpart.

Ms. KATZEN. I've seen the Johnston amendment, yes.

Mr. ZIMMER. If that was a freestanding bill, what would your position be?

Ms. KATZEN. My problems with the Johnston amendment are that it's limited only to EPA, so it is underinclusive, it applies to all regulations issued by EPA, including the most routine so it is overinclusive.

Mr. SYNAR. Mr. Zimmer, you will have that opportunity to ask Ms. Goldman when she comes up here with the administration's position. She's on the third panel.

Mr. ZIMMER. Good. Thank you, Mr. Chairman.

So your personal position is that one of your objections to this amendment is that it's underinclusive, that it only applies to EPA, and that subject to a de minimis exception, your personal position is that this is an acceptable approach, so long as routine regulations and regulations without major economic impact would be exempted.

Ms. KATZEN. If you're asking for my personal opinion, my personal opinion is that the statements put forth represent sound, good government, with the two caveats that I have given you. But casting those statements in legislation is not good government. This is a subject which has traditionally been the prerogative of the executive branch, has traditionally been incorporated in Executive orders, and I personally believe that that is the appropriate route. Whether that would lead to the administration's opposing the Johnston amendment as a freestanding bill, I cannot now say.

Mr. ZIMMER. But to summarize your position, you don't think it goes far enough, but you don't think it ought to be a law at all.

Ms. KATZEN. I don't think it should be in legislation.

Mr. ZIMMER. I think I understand. Let me draw your attention to the recent report issued by the National Academy of Sciences that criticized EPA for being too exhaustive in the cost-benefit analysis that it currently undertakes and suggested doing some back-of-the-envelope analyses, where that's warranted.

Now, is there room in the Executive order to do that? What do you think of the NAS criticism, and are you responding to that concern?

Ms. KATZEN. I think Dr. Goldman will be in a position to respond to that because EPA is specifically charged with reviewing and responding to that report, and I don't want to steal her thunder.

Mr. SYNAR. The gentlemen's time has expired.

Mr. ZIMMER. Thank you.

Mr. SYNAR. The gentleman from South Carolina.

Mr. SPRATT. Thank you very much, and thank you for your testimony.

Just quickly, as I understand it, what you're saying here is that we shouldn't elevate risk assessment to a status it doesn't deserve because it's still a fairly primitive science, and—you don't agree with that?

Ms. KATZEN. No. I believe in risk assessment. I believe in risk analysis. I believe in risk management. I believe in risk communication. I think they're important issues. We are doing an enormous amount to enhance risk analysis. We're pushing them as far and as fast as we can.

At the same time, I do not believe these principles should be in legislation because legislation may freeze our progress. The kinds of issues that are being discussed, I think, would benefit from continuing attention, continuing dialog, and continuing exploration. It's not unimportant; rather, it's very important and I don't want to get it wrong.

Mr. SPRATT. Well, what I was getting at is whether or not you think it's a mature analytical method that can be adopted and used by the government, or whether it stands——

Ms. KATZEN. I believe in risk analysis. I think it is a viable tool. I think it is a valuable tool. I think it's important.

Mr. SPRATT. Do you also think that it could stand improvement and that the government needs to focus resources upon it to improve it as an analytical method?

Ms. KATZEN. We need to focus on the implementation.

Mr. SPRATT. Let me give you an example. The government helped develop cost-benefit analysis. The Corps of Engineers created cost-benefit analysis, the conceptual framework for it. But it was a pretty soft field for a long time, until economists like Marty Feldstein came along and took it and they rigorously worked out the implications of it—such as what's the right social time preference rate? How do you do shadow pricing? All of these elements of it, they took and rigorously worked out.

Is the government pursuing this kind of rigorous validation of the techniques of risk assessment, or do we just have a soft notion of what it is? Do we just simply broadcast the idea and tell each department to go do it?

Ms. KATZEN. I think the kinds of statements that have been incorporated in the various amendments are the soft treatment; the kind of work we're doing is the difficult analytical work. I mean, we could discuss for hours whether you extrapolate data from a mouse to a man based on body weight or surface area. That is something which is gripping the attention of those who spend their lives on this subject.

We're not going to solve these problems at the level, that is put in legislation. Yet our offices are working on the tougher issues of implementation. Earlier I talked about a series of memorandums, which will be addressing those kinds of implementation issues.

Mr. SPRATT. Let me ask you this. Rather than ask you to comment on legislation which is not before you, there's an idea or concept before you, and the testimony Judge Breyer has filed. He says

it would make sense, he thinks, to have a select group of civil servants who are dedicated to this purpose, whose object and role is risk assessment, cost-benefit analysis. They become expert at it. They further the science. They develop the methodological technique.

Do you think that's a good idea? Without looking at the fine print, is that a good idea?

Ms. KATZEN. I think Judge Breyer's ideas are almost always fine ideas, and this is one that I support. He would have people spend some time in an agency and learn how regulations are developed some time in my office and learn how the oversight function works, and some time on Capitol Hill and see how the legislative part works. The development of the professional regulator, I think, is a superb idea. The seeds of it are in our regulatory working group, and we're already establishing such a program within the administration.

So I agree with the concept of expanding one's horizons to include all of these disciplines.

Mr. SPRATT. Thank you very much.

Mr. SYNAR. Mr. Sanders.

Mr. SANDERS. Thank you, Mr. Chairman.

Ms. Katzen, I find myself in a little bit of a quandary, for the following reason. I consider myself a very, very strong environmentalist, and in fact, would like to see the EPA be far more aggressive than it has been in the past.

There are two instances in which I have been in contact with EPA and have worked, one of them having to do with a polluted canal in Burlington, VT, and one of them dealing with off-gassing of carpets and the causation of illness as a result of that.

The EPA has performed, in both instances, rather disastrously and slowly. So I find myself wanting the EPA to do more, and based on what I have seen so far, not being terribly impressed by the efficiency of what the EPA has done.

In terms of risk assessment, let me ask you a question. In my State, especially in our schools, we have, I believe, a serious problem with indoor air pollution. Some of the schools have literally closed down for short periods of time. Nurses tell me that a lot of kids are coming down with asthma. There's a significant increase in asthma which may—underline "may"—be related to the quality of indoor air.

In our State of Vermont right now, it is 15 below zero. The buildings are built very, very tightly. There's been the introduction of a whole lot of new chemicals into buildings.

When we talk about risk assessment, how much importance is given to sickness? In the equation, how important is it? How much are you assessing the number of children in my State and throughout the country who may be becoming ill as a result of chemicals in our indoor air environment? How do you calculate that?

Ms. KATZEN. Dr. Goldman will be in a better position to respond, but it is an important point, that such illnesses should be considered. When Senator Johnston was talking about lives saved for $1 trillion, it's important that the issue is not solely that of mortality. Quality of life is an important factor. Certain hazards could leave you gravely injured or could affect your reproductive systems or

your respiratory systems in a way that really, truly impairs the quality of life. So to talk only about lives saved is too narrow a lens to look through in addressing the effects of a hazard. EPA has been taking such an expansive view of the effects of various hazards. Lynn Goldman may be able to expand on that.

Mr. SANDERS. I'm getting a little bit away from the subject here, but the concern that I have in risk assessment, to the best of my knowledge, every year, many, many very powerful chemicals are being introduced into our environment. Is that correct?

Ms. KATZEN. You're really moving into the field of Dr. Goldman, who is head of the toxics office at EPA and could answer these questions with far more precision than I could. I'm sorry.

Mr. SANDERS. I look forward to hearing the answers from Dr. Goldman. Thank you.

Thank you, Mr. Chairman.

Mr. SYNAR. Ms. Brown.

Ms. BROWN. Thank you, Mr. Chairman. I have a statement that I want submitted to the record.

Mr. SYNAR. Without objection. We'll keep the record open for all statements.

[The material can be found in the appendix.]

Ms. BROWN. I just want to say that although I support the general merits of risk assessment, I don't think this organizational bill is the vehicle to do that. And in fact, this amendment is what has really slowed down this bill from being passed during the first session of Congress.

And I'm hoping that we find the appropriate vehicle to do this. Elevating EPA to the top tier of the U.S. Government as an equal member of the President's Cabinet of advisors must happen before we consider other environmental legislation, such as the Clean Water Act, Safe Drinking Water Act, and Superfund.

Cost benefit, risk analysis, taking private property, wetlands, and other issues that affect existing environmental statutes go beyond the scope of this bill. So I would just like to submit my comments for the record.

I support the President in elevating EPA as a clean organizational bill.

Mr. SYNAR. Thank you. Mr. Condit for one more question.

Mr. CONDIT. Thank you, Mr. Chairman. I would like unanimous consent to submit for the record questions from Mr. Hayes to Dr. Goldman and Ms. Katzen.

Mr. SYNAR. Without objection.

[The information can be found in the appendix.]

Mr. CONDIT. I do have one quick question. Senator Johnston was here earlier and he said, and I'll quote from his statement, "I want to assure you that I'm amenable to limiting the size and type of regulation that are subject to the amendment, and look forward to resolving this issue in conference."

If the Johnston amendment were amended to include only those regulations that have the impact of the $100 million that Mr. Clinger made reference to, how much would it reduce the cost of compliance and has the agency done any calculation on this?

Ms. KATZEN. I believe Dr. Goldman may have some information on that. We have not considered that, since it was not previously presented in what we were asked to comment on.

Mr. CONDIT. OK. Well, I'll ask Dr. Goldman the question, as well. Thank you very much, Ms. Katzen.

Mr. SYNAR. Thank you. And Ms. Katzen, thank you very much for your patience and time today. It's been a long morning, so we appreciate that and look forward to working with you in the future.

Ms. KATZEN. Thank you, Mr. Chairman.

Mr. SYNAR. Our next panel is the Honorable Stephen Breyer, Chief Judge, First Judicial Circuit Court of the United States, Boston, MA; Roger Hirl, president and CEO of Occidental Chemical; Randy Wood, director of the Department of Environmental Quality, Lincoln, NE, on behalf of the National Governors Association; Dr. Adam Finkel, National Risk Reduction Program, Resources for the Future; Dr. John Wargo, associate professor of environmental policy, Yale University; Dr. John Graham, Center for Risk Management, Harvard University; Dr. Robert Percival, University of Maryland School of Law.

By the way, I need to tell Ms. Katzen and others, because this is a dual hearing with Mr. Conyers, we have foregone the swearing in of witnesses.

Gentlemen, thank you for being patient with us. As you can see, it is a very important hearing. We need to begin discussing this subject and let our colleagues speak out about it.

Please limit your oral statement to 5 minutes so we can get to questions and explore some of these issues. Judge, why don't you go first?

STATEMENT OF STEPHEN BREYER, CHIEF JUDGE, FIRST JUDICIAL CIRCUIT COURT OF THE UNITED STATES, BOSTON, MA

Mr. BREYER. Mr. Chairman, thank you for the opportunity. I'll take less than 5 minutes.

The book that I wrote is what you might have written if you'd spent about 2 hours every morning—because you had to give some lectures in front of your colleagues at Harvard a frightening event—for about 1½ years reading the science literature. Scientists write just like lawyers. Sometimes they write even better. I summarized what they had written. My book is a summary of where I saw the scientific mainstream.

My testimony is a summary of the book. Now, you would like me to summarize the summary of the summary. OK. I already hear a summary of the summary of the summary in your opening statement.

First, I agree with you. There is a problem. The problem is big. It has several aspects. On the one hand, we spend a lot of money dealing with risks that are awfully tiny, sometimes insignificant. On the other hand, there are some big problems in the area of health, safety, and the environment that we are not spending enough money on.

I would call it a problem of priorities. The issue is how can we save more lives?

Second, the causes are complicated. They're complicated because we live in a democracy. People ought to tell the government what

to do. At the same time, in the next century, much of what we shall do is highly technical, and none of us are really scientists.

If you hear on the radio that dioxin is a carcinogen, you think it is bad, don't swim in it. But, what about a molecule of dioxin? How bad is that?

Unless the public wants to undergo a course in risk analysis, it will never be able to answer that question, but, as a society we must answer that question if we are to give the public the safety that it wants and needs.

Congress has limited time, and many issues. To what extent do you want to go into the details? To what extent can you do so. How many hearings can you have on the details? What kinds of bills do you want to write with what degree of specificity, in a world where nobody trusts anybody? Do you want to write statutes that describe amounts of dioxin SO-4 down to the 14th molecule? You want to write that into legislation, when the science is going to change tomorrow? It's difficult for Congress to do, and it's difficult for the public to understand, and it's difficult for the regulators.

The third point is that I think you are right to focus on the regulatory system, and ask whether there's a way to inject greater sensitivity to priorities. And by that, what I mean is do not cut back 1 inch from the Nation's commitment to health, safety, and the environment. But rather, use that commitment in a way that protects the environment more effectively and saves more lives.

My fourth point is that unfortunately, I don't see a good way to bring that better priorization about in the short run. I think that what we're going to have to do is go back to the approach of FDR's new deal. That's pretty unpopular now, in a world where the public doesn't trust the government. But we must delegate—remember that new deal idea—to administrative agencies the discretionary authority to do some of this prioritizing. Control the regulators a little less, rather than a little more. But the President has been elected to do the health and safety job. If he doesn't do it, people can vote for another person. But give the President the legal authority to do it, and judge him afterwards according to whether or not he exercised his delegated power in a way that saved more lives.

What Ms. Katzen said is completely right, in my view. I think what they need in the White House is the legal authority to do the prioritizing. And when we were talking about different people from different disciplines, I also think that in the long run, in the medium run, and in the short run, it would be helpful to bring in some people with experience at EPA, who know the science, as well as the regulation, as well as the law. Bring some of them right into OIRA. Indeed, create a career path so that people could be trained over 10 years, having worked in a line agency, having worked at the center, and, I would hope, having worked in Congress, so you get the kind of person who understands a little about politics and government, as well as science, the problems of the regulators, and law, and the problem as seen from the center, as well.

That's the kind of reform I propose. Those are my four points.

[The prepared statement of Mr. Breyer follows:]

Testimony of Stephen Breyer
before The House Committee on Government Operations,
the Subcommittee on Environment, Energy and Natural Resources,
and the Subcommittee on Legislation and National Security
February 1, 1994

Mr. Chairman,

My name is Stephen Breyer. I am very pleased to have been invited by the Committee to discuss the subject of risk regulation. It is a subject that has long interested me: I have recently written a book about the federal regulation of substances that create health risks, and have taught risk regulation in administrative law courses for a number of years.

I would like to focus my comments today on the regulation of risks to health which are fairly small or uncertain. The best device I have found for explaining the term "small risk" is the "risk ladder" prepared by Robert Cameron Mitchell of Clark University. (Chart 1). Most people want to ask, "One death out of one million persons -- is that a lot or a little?" While there is no good answer to that question, Mitchell uses a "cigarette equivalency" table, shown at the right of the lower-level risk ladder. It indicates that the risk of being hit by lightning is the same as the

risk of death from smoking one cigarette once in your life, and it grades other risks accordingly. For present purposes, one should keep in mind that many of the regulatory risks addressed by current regulatory efforts are in the "blown-up" small risk portion of the ladder.

Small risks often, but not always, involve cancer. Of the 2.2 million Americans who die each year, about 22 percent, or 500,000, die of cancer. According to authorities Richard Doll and Richard Peto, smoking-related cancer accounts for 30 percent, or about 150,000, of those 500,000 deaths, while pollution, "occupation," and industrial products account for under 7 percent, or less than 35,000 of all cancer deaths. (Chart 2).

Small risks are currently being regulated by no less than twenty-six different statutes administered by at least eight different agencies. The regulatory system federal agencies employ to address and manage these risks consists of two basic parts: a technical part, called "risk assessment," or the art of predicting risk, which is designed to measure the risk associated with a given substance; and a more policy-oriented part, called "risk management," which decides what to do about the risk that the assessment reveals.

I have four propositions that I would like to present to you today regarding the regulation of small or uncertain risks.

My first proposition is that our regulatory system

badly prioritizes the health and environmental risks we face. Tunnel vision, a classic administrative disease, causes agencies to focus so single-mindedly on a given goal for a given substance -- say, the "complete" cleanup of a toxic waste dump -- that they impose ultra-stringent standards to neutralize the last, tiniest bit of risk posed by the substance. Because of the slightness of the risks involved, the strict standards impose high costs without achieving significant additional safety benefits. Moreover, critics complain -- rightly, in my view -- that agencies lack strategies for determining which of the more than sixty thousand chemical substances potentially subject to regulation are likely to need testing and which are not. In the absence of such a strategy, regulators tend to overemphasize known cancer risks --as compared to other, possibly greater risks, such as the risk of neurotoxicity, which can cause brain damage. If you add to this lack of a rational agenda the fact that agencies use different methods for estimating the effects of their regulations, attach widely varying values to the saving of a statistical life, and often ignore the safety effects of their own programs on other programs, you end up with a prioritization schedule that is skewed and irrational.

My second proposition is that we can practicably try to eliminate only one of the three causes of this prioritization problem. The three causes of the prioritization problem are the public's often-times irrational

reaction to risk, Congress' attempt to regulate risk directly through detailed statutory instructions, and the uncertainties and irrationalities of our technical regulatory methods. Together, these three phenomena reinforce one another to create a "vicious circle": they diminish public trust in regulatory institutions and thereby inhibit more rational regulation. Breaking that circle requires attacking it at its weakest point. Given the extreme difficulty of changing human psychology, press reactions, or Congressional politics, I think it clear that the weakest point of the circle is its regulatory link. I am convinced that we can best try to reform the risk regulation system by restructuring the executive branch institutions that run it so as to bring about technically better results. Insofar as a change in administrative organization would bring about technically better results, regulatory decisions would become somewhat more legitimate, thereby earning the regulator an added amount of prestige, which might in turn mean an added amount of public confidence. Any such increase in public trust might encourage greater legislative respect and delegation, which could help to further rationalize risk-regulation programs and expenditures. Increased rationalization would better the technical quality of the results achieved, enhance the agencies' prestige, increase public confidence, and so forth, until we found ourselves revolving around a new, now positive and beneficial, circle.

My third proposition is that an institutional restructuring of the regulatory system will help us only if it rationalizes the heart of the administrative effort -- risk assessment and risk management. These two areas are currently failing us. Risk assessment, though a scientific enterprise, does not involve scientists doing what they do best, namely developing theories about how x responds to y, other things being equal. Rather, it asks for predictions of events in a world where the "other things" include many potentially relevant, rapidly changing circumstances, requiring the expertise of many different disciplines to reach a conclusion. In order to reach such conclusions, scientists must make simplifying assumptions, but these assumptions can produce questionable results. Assumptions may, for example, tend to "err on the safe side" by assuming a linear relation between dose and response; by reporting animal test results in terms of upper confidence levels (i.e., no more than X number of persons will die from Y dosage amount); by overlooking potentially relevant differences between test animals and humans; and by working from average exposure levels. On the other hand, they will sometimes understate risks to multiply-exposed, or more sensitive, individuals. The possibilities of understatement and overstatement do not cancel each other out. The upshot is a system of risk assessment that may work well for assessing many large, serious risks, but where small risks are at issue it will generate results likely based on

a host of controversial assumptions.

The risk manager must then take a problematically crafted risk assessment, and, in light of its conclusions that a substance, say a pesticide, is a "known" or "suspect" carcinogen, ask such questions as (1) What will it cost to ban the substance? (2) What benefits would we thereby lose? (3) Would a ban create other significant risks? (4) What are the practicalities of enforcement? The answers to these questions also involve assumptions, guesswork, and subjectivity. In order to be good answers, they cannot simply represent the results of a mechanical system. Rather, they need to be informed by judgment, by the sound judgment of persons who by virtue of their training and experience are able to draw on a knowledge of science and economics, a feeling for the public's values, and a sense of administrative constraints. The institutional challenge for us is getting such persons in positions of authority. Currently, they are <u>not</u> in positions of authority, primarily because Congress has created different safety regulatory programs at different times, under different circumstances, with differing statutory language, administered by different agencies with different institutional environments employing different scientists from different disciplines.

<u>My fourth proposition is that we should look to the virtues of civil service administration for the rational judgment that we need to apply in tandem with our technical</u>

tools. What I have in mind here is the establishment of a new career path that would provide a small, centralized administrative group of civil servants with experience in health and environmental agencies, Congress, and OMB. By virtue of an interagency jurisdiction and a degree of political insulation, such a group would be in a position to create an improved, coherent risk-regulating system, adaptable for use in several different risk-related programs. It would be in a position to create priorities within as well as among programs, and to compare programs to determine how better to allocate resources to reduce risks. It would, in short, have the expertise and the insulation necessary to provide leadership on the myriad types of judgment calls that risk-regulation entails.

I do not think that we can generate this type of needed leadership from any source other than an expert group of civil servants. We cannot, for example, rely on detailed legislation to do the job of producing rational judgments on matters of risk. Where statutory language is so specific as to micromanage the administrative decision, it amounts to a set of shots in the dark. Specific language tries to set in stone the judgment calls that by nature must change to reflect changes in circumstances, values, and new discoveries. It mandates a certain degree of attention and detail to certain problems of risk -- when in fact what we need to do is give our decisionmakers the authority to look at the risk problem

at hand and then decide, on the basis of their best judgment, what level of response the problem merits.

In the end, my four propositions boil down to this: however sophisticated our math and our science are, they cannot make our risk-regulation decisions for us. To make those decisions, we have no choice but to employ our judgment. And to best employ our judgment, we need a well-trained civil service operating under statutory mandates broad enough to permit them to implement a sensible system of priorities. If this sounds like something of a call to return to the New Deal -- perhaps a New Deal informed by Science Advisory Boards -- that is precisely what I have in mind.

I should like to add just two more points. The White House has recently issued an Executive Order (September 30, 1993) that, among other things, calls upon agencies to set regulatory priorities in light of the degree and nature of the risks posed by the various substances or activities in their jurisdictions, and to base their regulatory decisions on a number of considerations rooted in several different disciplines. It seems to me that this Order is an important step in the right direction.

Second, I have thought that it might be helpful to put together an appendix of the sections of my recent book which are most relevant to my discussion today. The appendix fleshes out some of the concepts I have tried to address here, and thus may put my comments in a more understandable light.

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[An appendix to Judge Breyer's testimony has been filed for the record in the office of the Subcommittee.]

Mr. SYNAR. Dr. Finkel.

STATEMENT OF DR. ADAM M. FINKEL, FELLOW, CENTER FOR RISK MANAGEMENT, RESOURCES FOR THE FUTURE

Dr. FINKEL. An unenviable task, getting up in the morning and following Judge Breyer.

I assume what we're here to really talk about is whether Congress should step in at this point to try and "fix" risk assessment. And based on the proposals I've seen and the testimony today and some of the testimony at previous hearings, I guess I would have to advise against legislative action at this point.

Now, I say that not at all as a skeptic or an opponent of risk assessment, or as somebody interested in delay. I am devoted to improving risk assessment and I want to see it used more routinely for standard setting and priority setting. And I recognize that there are plenty of aspects of risk assessment that need to be fixed before Congress and the public can use it to its full potential, while remaining aware of its limitations.

But I think the path that we may be going down represents a fixation on some nonproblems, with some counterproductive solutions to these problems, combined with an avoidance of some of the real problems of risk assessment and management.

As a member of the National Academy of Sciences committee on risk assessment of hazardous air pollutants, or CAPRA, whose report came out a couple of weeks ago after a 2½ year process, I was tempted just to come here and say that now is not a good time for Congress to step in.

Our report contains more than 70 specific recommendations that our committee feels should go a long way toward improving some of the problems with risk assessment. We stress the need to tailor the detail and precision of each risk assessment to the importance and the sensitivity of the decision at hand, and we examine in detail six so-called cross-cutting issues that arise in risk assessment. We emphasize throughout that risk predictions are inherently "three-dimensional." They consist of: (1) the number; (2) the extent to which that number could be in error, either high or low—namely the domain of uncertainty; and, (3) the extent to which individual members of the population face risks either above or below any estimate you could generate—the domain of variability.

Thus far, EPA has been calculating and communicating to decisionmakers, Congress, and the public only one of these three dimensions, and I think our report seeks to end that practice. But I hope the subcommittees will not dismiss the suggestion to let this process work as something parochial or a plea for our group to take credit for it.

Indeed, if the legislation reinforced what we were doing or added to it, my own personal view is that there's no reason not to have more actors involved. But my own opinion is the problem with the proposals is they undermine the improvements that I and the committee thought were necessary, in part because they're based on some false premises. So let me just mention two of those in the time I have.

The first one is this emphasis in the bills and, in fact, in the Executive order, on this notion of the "best estimate" or the so-called

"objective estimate." I think there are at least four problems with this idea. Each one, by itself, would cast some real doubt on the wisdom of this concept.

The first one is the false premise. Who says that the current procedures give unrealistic estimates in the first place? It's a view that's just repeated ad infinitum, but it's based on a belief, which may someday be supported by evidence, that because some of what EPA does injects "conservatism" into the process, that the outputs have to be unrealistic. But for now, the only hard evidence we have, both on the exposure dimension and on the human biology, suggests that the outputs of EPA's models are not particularly conservative, on average.

The second problem is that the best estimate is also biased, or nonobjective, if you will. Both the conservative estimates and the "realistic" estimates are legitimate answers to different questions, and they both carry with them very specific and very value-laden assumptions.

For example, if we're going to use the analogy of driving to the airport, a best estimate of the time it would take to get there answers a question, and that question is: What estimate should I use if I want to get to the airport either just before or just after the plane takes off?

A conservative estimate answers a different question: What estimate should I use if I would rather be a fair amount early than a little bit late?

Now, a third problem, which is related, is that generating one of these best estimates and then adding a margin of safety to it doesn't give you a safe decision. It's arbitrary if all you know is the best estimate and you don't know what the margin of safety is trying to make you safe from. I'm not an engineer, but I assume that when a planner goes to an engineer to build a bridge, he doesn't say, "Just tell me how strong the bridge has to be in order to just barely hold up under the normal traffic, and leave it up to me to make it a stronger bridge."

And finally, some of the best estimates that are called for or envisioned in the legislation are basically unscientific contrivances that only make the numbers smaller and don't make them necessarily better. I have a couple of appendixes in my testimony that show this. I think there are three different kinds of situations where you might want to hold up a best estimate. One of them, I think, is already taken care of in the CAPRA report. We call for a more central estimate with respect to one of these types of situations. It's the last one that I'm particularly concerned about because it represents calling for a new estimate that basically involves dividing EPA's number by the odds that scientists would give to the possibility that the risk is really zero.

Now, that seems to me to be unworthy of the English word "best," and it seems to me to be inviting the kind of hand waving that fuels the suspicion, which I think is an unfortunate one, that risk assessment is, in part, a voodoo science.

Mr. SYNAR. Dr. Finkel, your time has expired, so why don't we wait for the rest of it in the question and answer period?

Dr. FINKEL. OK.

[The prepared statement of Dr. Finkel follows:]

SOME SMALL STEPS FOR CONGRESS, SOME GIANT LEAPS—BACKWARDS—FOR RISK ASSESSMENT?

Testimony of Adam M. Finkel, Sc.D.
Fellow, Center for Risk Management
Resources for the Future[1]
Washington, DC

Before the Subcommittee on Environment, Energy, and Natural Resources
and the Subcommittee on Legislation and National Security
Committee on Government Operations
U.S. House of Representatives
February 1, 1994

[1] The views expressed herein are those of the author and not necessarily those of Resources for the Future or the Center for Risk Management.

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I take the central question of this hearing to be: "Should Congress step in and fix risk assessment?" Based on the proposals I've seen (H.R. 2910, S.110 and its companion in the House, and others), I would have to advise against any action at this time. I say this not at all as a skeptic or opponent of risk assessment; quite the contrary, I am devoted to improving risk assessment and seeing it used more routinely for standard-setting and broader priority-setting decisions. And, I recognize that there are plenty of aspects of risk assessment that need to be fixed before Congress and the public can use it to its full potential while remaining aware of its inherent limitations. But based on the legislation at hand and the testimony of other witnesses today and in previous hearings, I would like to warn the Subcommittees about what I see as a fixation on non-problems (or on counterproductive, simplistic solutions to real problems), combined with a studious avoidance of some of the real problems of risk assessment and management.

As a member of the National Academy of Sciences' Committee on Risk Assessment of Hazardous Air Pollutants (CAPRA), whose report was released two weeks ago following a 2½-year process, I was tempted to recommend simply that now is a particularly inauspicious time for Congress to step in. The CAPRA report contains more than 70 specific recommendations that our committee feels should go a long way towards improving some of the flaws in risk assessment; by law (the 1990 Clean Air Act Amendments), EPA must prepare a formal response to our recommendations. Our report stressed the need for an "iterative" approach to risk assessment (the need to tailor the detail and precision of each risk assessment to the importance and sensitivity of the decision at hand), and examined in detail six "cross-cutting" methodological issues that arise in all four of the intellectual stages of the risk assessment process that NAS identified in 1983. Perhaps the most far-reaching of the issues we identified are the related concepts of uncertainty and variability in risk assessment. Essentially, we emphasize that risk predictions are inherently "three-dimensional"—they consist of a numerical estimate, the extent to which the estimate could be in error, either high or low (uncertainty), and the extent to which individual members of the population face risks

above or below any estimate generated (variability). Thus far, EPA has been calculating and communicating to decision-makers, Congress, and the public only one of these three dimensions.

But I hope the Committee will not tend to dismiss my suggestion (I am not here speaking for the entire CAPRA committee, although I suspect many of our membership might agree with this point) that legislation should be tabled in order to allow EPA to implement our recommendations. If the proposals at hand reinforced CAPRA's recommendations or added to them thoughtfully, I suppose my concern would sound like a parochial plea for recognition and credit. But the problem is that the various bills undermine the needed improvements because they are largely based on false premises. In the remainder of my testimony, I will focus on two issues regarding risk assessment for setting environmental standards. I raise these issues only as examples of the kinds of misconceptions present in the various attempts to "fix" risk assessment—there are, unfortunately, several others I could have chosen. I will then conclude by briefly discussing my views on risk assessment for priority-setting, a concept that was outside of the charge to CAPRA.

Issue 1: The Sirens' Song of "Best Estimates"

Each of these four problems by itself would cast serious doubt on the wisdom of requiring EPA or other agencies to calculate and communicate "best estimates" of risk:

(1) Who says current procedures yield unrealistic estimates? This view, repeated *ad infinitum*, is based on the theory, which may eventually be supported by evidence, that because some of the assumptions EPA makes are admittedly "conservative," their procedures as a whole must yield unrealistically exaggerated outputs. But for now, the only real evidence we have, both of actual human exposures and of the cancer potency of chemicals in rodents and humans, suggests that current risk estimates are not in fact particularly "conservative."

(2) Best estimates are also "biased." Both "conservative" estimates and "realistic" estimates are legitimate answers to different, valid questions, and both carry with them very specific value-laden assumptions. For example, a central estimate of the time it would take to drive to the airport answers the question "What estimate should I use if I want to arrive either just before or just after the plane takes off?" A "conservative" estimate answers the question "What estimate should I use if I would rather be a fair amount early than even a little bit late?"

Figure 1 shows how three types of "best estimate" (and who will decide which "best" is "best" if and when they differ by orders of magnitude?) answer three different risk assessment questions with respect to uncertainty and with respect to how much of the population is considered for protection.

(3) Adding a "margin of safety" to a "best estimate" doesn't produce a safe decision. How can you be anything but arbitrary if all you know is the average risk and don't know what the margin of safety would help make you safe from? Planners don't ask engineers to "just tell me how strong the bridge needs to be to just barely hold up under normal traffic—leave it to me to decide how much more steel to add."

(4) Many "best estimates" are unscientific contrivances which only make the numbers smaller, not better. Figure 2 shows there are three different types of situations where current estimates could be supplanted by "best estimates." Problem 1 (parameter uncertainty) is already dealt with in detail by CAPRA, which directs EPA to quantify the full distribution and explicitly choose a central or conservative estimate based on the type and importance of the decision at hand. In Problem 2 (conflicting data sets), averaging all the data together may be a useful contrivance, but it dilutes the correct (but unknown) answer with various incorrect answers. "Including all relevant data" is a tautology if you don't know which data will turn out to have misled you—choosing some of the data based on concern for public health is no more value-laden than choosing to lump all the data together. In Problem 3 (fundamental scientific disagreement), the only alternative to "conservatism" is to divide EPA's number by the odds that scientists would give to the possibility the risk is really zero. This is not only unworthy of the English word "best," but it is the kind of hand-waving that fuels the unfortunate suspicion that risk assessment is a "voodoo science." The CAPRA committee agreed to recommend against this type of "best" estimate, preferring to reinforce EPA's use of "default" models that lead to a number or a distribution of risk based on a single coherent set of theories that will change over time in response to improved scientific information.[2]

It is important to note that although these examples all relate to uncertainty in cancer potency, CAPRA also made several recommendations regarding the appropriate amount of "conservatism" when estimating exposures which vary across the population. Although we recognize that in general, agencies should be free to choose to protect the average person (a "best estimate" accounting for variability) or any other fraction of the population, the Clean Air Act specifically refers to "the individual most exposed to emissions." We therefore provide

[2] I commend to the Subcommittees' attention the final appendix to the CAPRA report, which consists of two papers encapsulating a disagreement among the Committee as to how these theories should be selected and modified over time. We all regard these papers as essential input for decisions we urge EPA to make about how to use the available science to produce estimates that can legitimately be called "best."

mathematical guidance for how EPA should estimate this level of exposure, and note that this will require moving away from EPA's recent attempts to model a "reasonably high-end exposure" and to assume that when people change their place of residence they move to a location where exposure to all carcinogens is zero.

Issue 2: Judge Breyer's "Tunnel Vision"

Even though I maintain that much of Judge Breyer's recent book *Breaking the Vicious Circle* is founded on the unsubstantiated belief that all risk estimates are exaggerated, I do not dispute the possibility that health and environmental risks could be reduced much more rationally and efficiently. I will make what I hope is a constructive suggestion in this regard in a moment. But the urgency with which we need to roll back our attempts to reduce certain risks surely depends on how damaging these interventions are in economic terms. If eliminating a substance that might pose either large risks or no risk at all could be done with virtually no adverse impact on the economy or consumer welfare, then most people would agree it would be prudent to proceed, even in the face of the possibility that no real risk reduction might occur.

So one simply must ask the other half of the question: how real is the economic crisis created by our attempts to respond to what some say is a trumped-up health crisis? I conclude that we need to get our cost numbers straight before we spend too much more effort trying to debunk risk numbers. First of all, if one looks carefully at the history of what compliance was supposed to cost when advocates were trying to delay or overturn regulations, *versus* what compliance actually cost once they gave up fighting it, one might well conclude that this is the home of "cascading conservatism." The more general point is that the $150 billion (or whatever) spent on regulatory compliance is part of the economy, not a drain on the economy, unless you completely discount the economic benefits that accrue to suppliers of pollution control technology and producers of substitute goods. All regulations create winners and losers; sometimes the effects on the latter (far) outweigh the effects on the former. But one

thing is constant—the losers (and their advocates) organize and complain while the winners quietly go about their business. For example, when Alar was forced off the market, a minority of growers in certain regions of the country were hit hard, and a few of the ones in Washington State sued CBS News and NRDC for being the bearers of the bad biological news about Alar. The rest of the growers, whose economic gains were responsible for so offsetting these losses that the total industry revenues have doubled over five years since the ban, have not been heard from, and the predictions of consumer unrest due to poor-quality apples are now seen to have been groundless.

Thoughts on Priority-Setting

In contrast to the "steps backwards" the legislative proposals may take with respect to risk-based standard-setting, I am more supportive of Congressional action to promote risk assessment for setting national environmental priorities. However, I would characterize the Moynihan bill and similar proposals to rank risks for priority-setting as (to borrow a metaphor from Prof. Donald Hornstein) "out of the fire and into the frying pan." Many of the attendees at a conference RFF organized just after the 1992 election on "the EPA risk-based paradigm and its alternatives" came away believing that comparative risk assessment is an important first step towards setting more sensible priorities, but that it could be counterproductive to emphasize it over other equally useful paradigms or to press ahead unmindful of its limitations.

The "limitations" part is fairly easy to explain. On top of all the emphasis on how hard it is to compare two things numerically when the public may care deeply about many important factors the numbers can't convey, a more fundamental point has been missed (in both S.110 and much of today's testimony): it is much harder than most "experts" think to compare two numbers when neither number is known with any precision. For example, many people have used as an example of misplaced priorities the alleged "fact" that aflatoxin in peanut butter was 18 times riskier than Alar in apple juice. But in light of my own analysis of the uncertainty in these risks, which suggests that the true risk of aflatoxin might have been 300 times greater or

30 times smaller, the blanket statement of 18:1 is hardly informative, either quantitatively or qualitatively (it fails to admit the distinct possibility that the correct rank order is reversed). The limitations of comparative risk assessment, it should go without saying, only increase when less straightforward comparisons are attempted—in light of the 10,000-fold uncertainty about the relative risk of these two food contaminants, I would urge EPA and its advisors to think harder about whether, for example, radon so clearly poses "larger" risks than Superfund sites do.

The existence of other paradigms to set priorities is more controversial. Nevertheless, I believe the kind of risk ranking called for in the Moynihan bill is an answer to the wrong question. "Which risks are worst?" is an intellectual question; "what actions should we take right away?" is the practical question we need to ask in a time of resource constraints. I contend we can best get at the latter question not by ranking the symptoms of our problems (one risk versus another), but by exploring actions that address the causes themselves. I think a bill that encouraged all agencies to redirect attention towards well-defined actions that could abate multiple risks and prevent them from recurring would be a truly worthwhile focal point for Congressional activity.

FIGURE 1.....A. Finkel

ALL ESTIMATES ARE "BIASED"

		Risk Assessment	
Estimate	Airplane Ex.	Uncertainty	Variability
Mode (Most likely)	Max. probability of arriving just as plane leaves	Max. probability that risk is exactly "acceptable"	Protect "most common person"
Median	50/50 chance of catching or missing flight	50/50 chance intervention is too risky or too costly	Protect "typical person"
*Mean**	X minutes late = X minutes early	X units "overspending"= X units "underspending"	Protect population on average
95th %ile	X minutes late = 19 times worse than X minutes early	X units underspending = 19 times worse than converse	Protect persons at increased risk

**Note: mean can occur at any percentile; may even exceed 95th %ile*

FIGURE 2.....A. Finkel

"BEST" ESTIMATES—The Sound and the Fury

Hypothetical:

Test Group	# Tumors	Human Risk (linear)[1]
Male Mice	50/100	$1x10^{-3}$
Female Mice	10/100	$2x10^{-4}$
Male Rats	5/100	$1x10^{-4}$
Female Rats	1/100 (NS)	0

Using its current procedures, EPA would compute the upper 95th percentile of the response in male mice, giving a "plausible upper bound" risk of approximately **$1.16x10^{-3}$.**

Problem 1—Parameter Uncertainty:

The uncertainty distribution for human risk using a linear approximation from the male mouse data (i.e., the random sampling error given that only 100 mice were tested and the true risk to mice cannot be precisely known) is approximately normal ("bell-shaped"), with a mean of $1x10^{-3}$, a lower bound of $8.4x10^{-4}$, and an upper bound of $1.16x10^{-3}$. CAPRA recommends that EPA routinely quantify and communicate such distributions, and explicitly choose the "level of conservatism" desired.

[1] Assume exposures to humans are 500 times lower than the bioassay exposures.

Problem 2—Independent Data Sets:

Humans (on average) must respond biologically most like one of the four sex/species combinations; the uncertainty comes in not knowing which of the four it is. Choosing the most sensitive test group gives a 25% chance of being correct and a 75% chance of being "conservative" (for the average person, not necessarily for the half of the population with above-average susceptibility). But averaging all four rodent groups together gives a risk estimate ($3.3x10^{-4}$) that has no probability of being correct; it is less "conservative" but also less scientific in that more *irrelevant* data are considered.

Problem 3—Conflicting Scientific Theories:

Suppose scientists are divided over whether humans respond so differently from rodents to this chemical that the human risk at low doses is zero. Constructing a "best estimate" somewhere between the EPA number and zero requires determining the fraction of scientists who believe the EPA number is based on the correct theory, and multiplying that fraction by $1.16x10^{-3}$ (e.g., if the split is 50/50, the "best estimate" would be $5.8x10^{-4}$; if 95 percent believe the risk is zero, it would be $5.8x10^{-5}$). This raises two unanswered questions: (1) Who determines the factor used to dilute the "conservative" estimate?; and (2) If you forgot whether someone said to meet him on 8th St. N.E. or 8th St. N.W., would you wait at the Capitol (the one place you're sure *not* to find him)?

Mr. SYNAR. Dr. Wargo.

STATEMENT OF DR. JOHN WARGO, PROFESSOR OF ENVIRONMENTAL POLICY, YALE UNIVERSITY

Dr. WARGO. Mr. Chairman, thank you very much. I'm coming before you today as a professor at Yale University, with a joint appointment in the School of Forestry and Environmental Studies and the Department of Political Science. My area of expertise is in the area of science policy, and I have participated over the last 7 years in two National Academy of Sciences reports that I think are relevant to your deliberations today. One was the Delaney paradox report regulating pesticides in foods, published in 1987, and the second was "Pesticides in the Diets of Infants and Children," which was published this past summer.

I wrote in my testimony that the subject of today's hearing was risk assessment and the elevation of EPA to Cabinet status. I've since changed that topic, sitting here listening to people, to: what is the quality of reasoning that should precede decisionmaking, and how do you control bias?

I'm not going or review all of my comments that you'll find in my written statement, and I asked that they be incorporated into the record.

What's clear to me, from studying environmental law and EPA administrative behavior, is that the subject of risk estimation and management of risk is extremely central to the mission of EPA. It's their primary mission to estimate risks and to manage those risks.

And, as we've heard today, environmental law is fractured. It's been fractured by Congress, in that you've attempted to solve specific problems by type of toxic substance or by media that the toxic substance flows within—air, water—or by source. And the pursuit of scientific evidence about risk that underlies decisions to set standards in these areas can become a black hole for Agency resources.

We've seen, in the area of pesticide regulation, the control particularly of fungicides has often taken the Agency 10, 12, 15 years to make a decision, largely based on an argument that we don't have good enough scientific evidence.

I'd characterize the past 20 years of environmental law as a problem definition phase in environmental law. We broadly laid out what the problems are and we've broadly set up a framework for dealing with them. I'd characterize the coming era, the remainder of this century and the beginning of the next, as an era of what I would call strategic risk management. We need to focus. We need to focus our scarce resources on the highest risks, to achieve the greatest degree of risk reduction for the least possible social cost.

I thought I'd talk, just for a couple of minutes, about the dominant problems of risk assessment. One of the major problems is how to treat uncertainty in the estimates of risk? Uncertainty creeps into a risk estimate in a lot of ways, and because of that, the risk estimation process is subject to a lot of potential bias by those conducting the risk analysis. It can creep in in the design of our models of causality. It can creep in by virtue of the fact that we have poor quality data. It can creep in because we have an absence of trend data.

And risk estimation—I like that phrase, by the way, risk estimation, as opposed to risk assessment, because estimation reminds us that we're trying to project these damages out into the future, and it reminds us that there's a lot of uncertainty surrounding those estimates. We often don't have trend data that would support those projections.

And finally, there is uncertainty that creeps in in our choice of analytic methods.

When we conducted our analyses of pesticides in children, we found that you could basically conclude that a compound is very high risk or very low risk by choosing specific sets of data or specific methods of analysis. That means that in order for risk assessment to be a useful tool of government, to really reduce risks in society, health or environmental, that you have to control the quality of data, and you also have to control the methods of analysis. And it's very difficult for me to see how Congress could specify that in the form of regulation.

Another key lesson of the study on pesticides in children is that we need to look at distributional issues very carefully, how risks are distributed in society, which raises a very difficult regulatory problem. Are we going to design our regulatory standards to protect certain subpopulations and then apply that standard nationally?

I think that the conclusions of the Academy in this matter are extremely important and should be thought of with respect to different types of risks.

I'll conclude by a statement that I believe that the issue of risk analysis should be disentangled from the issue of elevating EPA to Cabinet-level status. I'd also like to strongly support the approach of incorporating strategic risk management planning that we see within the Executive order discussed earlier this morning.

I think also that the ample margin of safety concept is extremely prudent and should be applied regularly.

[The prepared statement of Dr. Wargo follows:]

Testimony of

Dr. John Wargo
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Before The:

Committee on Government Operations
Subcommittee on Environment, Energy and Natural Resources
Subcommittee on Legislation and National Security

House of Representatives

February 1, 1994

On the Subject of Risk Assessment and the Elevation of the Environmental Protection Agency to Cabinet Status

A. Introduction

I am honored to appear before you today to discuss the subject of risk assessment and its relationship to the mission of the Environmental Protection Agency. I understand that this hearing is being held as part of your general interest in the merits of elevating EPA to Cabinet status.

I am appearing here today as an Associate Professor at Yale University, where I hold appointments in the School of Forestry and Environmental Studies, the Political Science Department. My academic expertise lies in an area known as the science policy. Specifically, I research the relationships between science, analysis and environmental decisionmaking. I teach courses in environmental and health risk assessment and management to both graduate and undergraduate students.

Over the past 7 years I have conducted research on the risk assessment and management of pesticides and this research has become component of the deliberations and findings of two National Academy of Sciences Committees, resulting in two books. The first book, *The Delaney Paradox* published in 1987, exposed the double standard which is commonly applied to pesticide regulation, one is a zero-risk standard applied to processed foods, and the second a risk-benefit balancing standard applied to raw agricultural commodities. These standards make it more difficult to introduce new lower-risk compounds than to retain registration for older higher-risk compounds. The second book, *Pesticides in the Diets of Infants and Children* was released in June, 1993, and demonstrates that children are exposed to higher levels of certain pesticides, per unit of their bodyweight, and that they are physiologically more susceptible to certain toxic effects than adults.

B. Mission of EPA: Risk Estimation and Management

The estimation and management of risk is clearly central to the mission of the Environmental Protection Agency (EPA). It is the Agency's role to estimate risks of health and environmental damage, and to manage those risks guided by decision criteria contained within a very diverse body of environmental law. This mission has been defined largely by Congress with separate statutes targeted to specific problems, e.g. air quality, water quality, food safety, waste management, and toxic substance control.

Individual standards for allowable contamination are established based upon estimates of potential damage to health or the environment. Different laws contain different criteria for standard-setting. For example, the Federal Insecticide Fungicide and Rodenticide Act requires EPA to register pesticides if it finds will not pose "unreasonable risks to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide. The Federal Food Drug and Cosmetic Act contains a "risk-only" standard, allowing no residue of any food additive which has been found to induce cancer in animals or humans. The Clean Air Act controls hazardous air pollutants and requires emission levels to be set based upon a combination of technology based standards in combination with "residual risk" standards set to protect the public health with "an ample margin of safety". The Clean Water Act requires industry to install several types of control measures, including: "best practicable control technology, best conventional technology, best available technology economically achievable, best demonstrated control technology". Costs and other factors are to be taken into account in assessing technology-based control standards. The Toxic Substance Control Act requires EPA to consider the effects of a toxic substance on human health and the environment, the benefits of the substance, and the economic consequences of any proposed rule on the national economy, small businesses, technological innovation, the environment and public health.

In essence, Congress has broken the problem of environmental quality into numerous pieces, and there is no consistent standard for regulation across the problem areas. It is fair to say that our strategy to control environmental quality is fractured. It is fractured by environmental media (e.g. atmosphere, oceans, freshwater, food), by class of toxin (pesticide, hazardous materials and wastes, "toxic substances"), and by type of natural resource (forests, rangelands, croplands, energy, minerals, wildlife and fish). Science which is highly specialized and reductionist contributes to this fragmentation.

This regulatory system has resulted in an incremental approach to problem solving. This is a normal administrative response, particularly under conditions of scarce budgetary resources and significant scientific uncertainty. Scientific uncertainty can become a "black hole" for agency attention and resources. A narrower and narrower focus on incremental choices, such as how to manage a single toxin or single site causes the Agency to slow down its rule-making process, offering less and less opportunity to focus on broader and often more important issues of strategic cross-compound and cross-media risk management.

The past several decades could be characterized as the "Problem Definition" period in the history of environmental law. Through law and regulation we have designed a comprehensive system to manage environmental quality by type of media (air, water, food etc.) and by type of contaminant. What we have failed to do well in this era is to strategically identify the subclasses of problems which

appear to pose the greatest risks, and to effectively reduce these risks at what most would conclude to be a reasonable cost. The Superfund, RCRA Corrective Action and Special Review Program for Pesticides provide examples of substantial regulatory delay with high regulatory costs.

We are entering a period which I would like to call the "Strategic Risk Management" era. Here we must focus our scientific and regulatory resources to identify the most significant sources of risks within programs and across programs. We also need to direct our responses toward "cost-effective" management approaches...that is, we need to adopt policies which achieve the greatest reduction of risk at the least possible cost.

C. Dominant Problems of Risk Assessment

The central task of risk assessment, then, is to identify a range of possible outcomes (worst case to best case) and to assign an estimate of the likelihood of these outcomes occurring. Dominant problems of risk assessment are discussed below.

Uncertainty and Risk "Estimation"

I prefer the phrase "risk estimation" to "risk assessment" because the word estimation implies that the effect projected to occur is uncertain; it is an estimate. Estimates of future damage are always bounded by uncertainty. The uncertainty in any risk estimate is caused by a variety of factors including: a) error in our models of causality; b) poor data quality; c) absence of trend data; d) analytical methods which fail to represent risks as probabilities of different magnitudes of damage occurring. The quality of a risk analysis may often be judged by how carefully and honestly these potential weaknesses are expressed, and how they are translated into a statement of likelihood, or probability, that specific types, magnitudes and distributions of damages will occur.

Data Quality Problems

The quality of data available for exposure and risk assessment is normally far less than the level which would be optimal. Key categories of data vital to risk assessments include: a) the magnitude of contamination released to the environment; b) the distribution and fate of the contaminant in the environment; c) human exposure to the contaminant (by air, water, food); and d) the human response to the exposure, or the dose-response relationship.

For each of these categories it is likely that data will be of substandard quality, forcing EPA to make judgments regarding the need to a) collect better data and delay a decision; or b) hypothetically model the relationship. In most risk assessments, better data is sought and uncertainty is modeled using a variety of computer simulation and gaming techniques such as Monte Carlo-type analyses. The quest for higher quality data and more accurate models of causality is a fundamental explanation of regulatory delay.

It is also important to disentangle the concepts of data accuracy, variability and projectability. First, accuracy of data is derived from the quality of its reflection of the real world. Poor sampling design, collection and storage methods will contribute to uncertainty. Second, data sets normally contain variability, i.e. whatever is being measured is found in the sample to lie at different levels. Third,

the reasonableness of projecting past trends (measured in data sets) to the future must also be considered. These three issues, accuracy, variability and projectability are crucial components of the uncertainty which surrounds risk estimates.

Methodological Problems

Methods of assessment are often structured to produce summary statistical analyses of exposures and risks to broad populations. These methods often result in single point estimates of risk (e.g an increment of U.S. average cancer risk of 1 in one million). These types of summaries are potentially dangerous and misleading as they fail to capture the full distribution of exposures and risks, particularly for sensitive populations at risk such as children, the elderly or infirmed. Summary statistical analyses (for example, estimating average or even 90th percentile levels of exposure) are clearly inadequate. Software could be designed to meet these specific needs for both chronic and acute exposure and risk assessment. What we really need is a clear sense of the bounds of risk. What is the worst case, what is the best case, and what is the chance of falling at various stages in between. Risk projections should be represented as probability distributions to provide the Administrator with the richest possible sense of the range of possible outcomes.

Assumptions

Estimates of risk also vary due to the specific set of assumptions regarding choice of data set, and choice of analytical methods and models. Conservative assumptions may be combined and demonstrate that risks are high and that standards have been breached. Moderate assumptions may be combined to demonstrate that risks are modest and that risks are beneath regulatory thresholds. A history of political manipulation of these assumptions has lead certain Senators and Congressmen to propose legislation requiring the use of conservative or "default" assumptions to be used in risk assessment. These assumptions would apply under conditions of uncertainty, and would presumably be relieved in the face of scientifically credible evidence demonstrating lower levels of exposure or dose-response.

The analysis of Benomyl presented in the NAS report, Pesticides in the Diets of Infants of Children demonstrates the enormous effect which assumptions about Benomyl residues in food have on estimates of childhood exposure to Benomyl, and rates of childhood cancer risk accumulation. The residue date set you choose, (market basket, warehouse, field trial etc.) governs your conclusion regarding whether or not a risk ceiling has been breached.

Distributional Issues in Risk Estimation

The recent National Academy of Sciences Study, *Pesticides in the Diets of Infants and Children* identifies the potential for childhood exposure to pesticides, and their potential to be more susceptible than adults to the toxic effects of pesticides. This type of analysis should be conducted for other types of toxic substances, and poses a particular problem for regulators. Should national standards be structured to protect the most exposed and susceptible subpopulations? I think the answer is yes.

The Complex Mixture and Multi-Media Problem

We are all exposed to a complex mixture of contamination on a daily basis from different media, i.e. food, water, air etc. Methods of estimating exposure and the toxic effects of mixtures are often primitive, and are likely the result of law and regulation which generally is directed to the single-media regulation of chemicals, one-at-a-time. Real world risk reduction will require formal scientific and legal consideration of multi-media exposure to complex mixtures of toxic substances.

D. The Cost-Benefit Question

Cost and benefit estimation poses many of the same analytical problems described above for risk estimation. Just as there is great debate over the appropriate methods to use for risk estimation, there is also great debate over how to conduct cost and benefit analyses. What types of costs and benefits should be considered? What methods should we use to estimate the loss of health, a life, a job? How far into the future should we estimate these effects?

Consider cost-benefit analysis of pesticides as an example. What is the net social value of pesticide production and use? If the government must weigh risks against benefits before registering a pesticide, how are social benefits and costs calculated? What kinds of benefits should be considered: crop damage avoided, jobs, balance of trade? How should the costs of pesticide use be factored into an estimate of "net benefit"? These costs might include contaminated groundwater, drinking water filtration, government residue testing in foods, drinking water quality monitoring (currently estimated at over $1 billion/year), health care costs for those poisoned, clean-up of production sites. What time frame should costs and benefits be calculated within? A short-term analysis tends to exaggerate benefits, while a longer term estimate will elevate the relative importance of costs. Finally, and perhaps most importantly, what is done with the result? How are risks and benefits balanced, given their expression in incommensurable units? These questions should not lead one to conclude that conducting cost and benefit analyses is fruitless. The opposite is clearly true, they are necessary for informed decisionmaking, although they will not often provide clear guidance particularly when both health risks and the costs of regulation are estimated to be high.

E. Comparative Risk: Defining the Context for Analysis

The Johnston Amendment requires "a comparative analysis of the risk addressed by the regulation relative to other risks which to which the public is exposed." While on its face this may seem reasonable, it constitutes an enormous analytical burden to estimate the relative dangers facing humanity.

Our knowledge about relative dangers is extremely uncertain, due to all of the issues raised above concerning primitive methods of analysis and uncertain data. Meaningful comparison of risks across types of problems assumes that we may reduce damages to a common metric to judge relative danger. While my economist friends will argue that this common metric is monetary, there is enormous variation in estimates of costs of health and environmental loss. In short, the Amendment demonstrates enormous faith in human rationality-but this is a faith which would quickly turn into an analytical nightmare, if applied to each regulatory choice before the EPA Administrator.

As an alternative strategy, I would suggest that Congress fund the production of an annual report on comparative and relative risks, placing risks from each of EPA's major programs within this broader context. This research would serve a valuable function of exploring methods of risk estimation and evaluation, and would provide the Administration with a valuable rational foundation for its annual legislative agenda.

F. Risk Management Issues

The *De Minimus* Problem

The difficulty of managing a *de minimus* or "trivial" level cancer risk is particularly acute in pesticide regulation. Two laws provide a confusing and contradictory framework for managing cancer risks associated with pesticides. The Food, Drug and Cosmetic Act prohibits the existence of any pesticide residues found to induce cancer in animals or humans, however EPA has allowed small amounts of pesticide residues in food, if they determined that risks were trivial. The Ninth Circuit Court of Appeals overturned EPA's allowance of these *de minimus* risks, requiring a literal "zero risk" or "no detectable residue" standard to be applied to cases where pesticides concentrate during food processing.

This ruling has placed enormous pressure on EPA and Congress to amend the FFDCA to allow *de minimus* levels of risk, e.g. one cancer case in a million people exposed over a lifetime. Since variance in risk estimates is often enormous, how should risk be calculated to see if *de minimus* thresholds have been exceeded? Should methods of risk assessment and data quality standards be written into law or regulation? Where should a *de minimus* ceiling be imposed: on each chemical, crop or across the entire diet? What should be the temporal unit for allowable risk - one year or a lifetime? Formal adoption of a risk ceiling as a management strategy (e.g. one-in-one million cancer risk) must address these questions directly.

Managing Bias in Risk Assessment

In 1983, a National Academy of Sciences NRC Committee sharply criticized the variability of risk assessment standards within federal agencies in a report entitled Risk Assessment in the Federal Government: Managing the Process. Now, more than a decade later, it is clear that great variability in methods and standards remain. The NAS Committee responsible for the report suggested that federal agencies adopt an approach which clearly segregates the process of "risk assessment" from that of "risk management". This separation, the Committee argued, would "protect" science from politics. Since this report, most federal agencies have formally distinguished the "risk assessment" process which they believe to be scientific, from the "risk management" process, which they believe to be political.

This was a well-meaning attempt to protect the quality of science in risk assessments from hidden political biases and value judgments believed to be restricted to "risk management". Yet, biases may creep into the risk assessment process in numerous ways- in the definition of the problem to be addressed, in the choice of evidence, in the choice of methods for analysis, in the interpretation of uncertainty and in the selection of conclusions to be conveyed to the public. Real improvement in the quality of risk estimates could come from a requirement that biases, assumptions and judgments be formally exposed for public review.

G. Specific Recommendations

1. The Johnston Amendment

This amendment as it is currently written will lead to regulatory paralysis. While there is significant merit in promoting the quality of rational analysis underlying regulatory decisions, this comprehensive requirement would make demands upon the scientific resources of EPA which it could not bear without very significant additional funding.

2. Strategic Risk Management Planning

Strategic risk reduction will only be accomplished by a broader contextual review of the relative risks experienced within major EPA programs. A regulatory system which focuses on single compounds, one-at-a-time, has no hope of accomplishing cost-effective risk reduction. Congress should direct EPA to conduct programmatic risk assessment and management plans with a specific purpose of identifying sources of greatest risk and plans for its cost-effective management.

3. Ample Margin of Safety Concept is Prudent

Given the fact that the current system for managing human exposure to toxins: a) is slow-paced; b) rarely considers potential additive or synergistic effects of complex mixtures; c) sets allowable exposure levels based on factors such as benefit or technological feasibility, the use of safety factors, or ample margins of safety, seems to be a prudent management response.

4. Congress Should Fund Risk-Related Research

Significant additional research funding for improvements in risk assessment should be provided to EPA by Congress. EPA should have at the highest level an Office of Risk Estimation and Management to coordinate this research, and to ensure that EPA is directing its scarce regulatory funds toward reducing the most significant risks in the most cost-effective manner within and across program areas.

5. Role of the National Academy of Sciences

The NAS has played an important role in assessing the quality of science and effectiveness of law in managing environmental and health risks. Two excellent examples of the contribution of the Academy include the recent reports on pesticides and hazardous air pollution. I would encourage Congress to require a more systematic cross-program evaluation of risk estimation methods and management effectiveness.

6. Full Disclosure

EPA should be required to fully disclose the data sets and methods of analysis used to estimate risks, costs and benefits associated with "significant" regulatory decisions. The effect of full disclosure will be to improve quality of analysis used to justify decisions.

Mr. SYNAR. Thank you, Doctor. Professor Percival.

STATEMENT OF ROBERT V. PERCIVAL, ASSOCIATE PROFESSOR OF LAW, UNIVERSITY OF MARYLAND SCHOOL OF LAW

Dr. PERCIVAL. Thank you, Mr. Chairman. Former EPA Administrator William Ruckleshaus once said that risk assessment can be like a captured spy. If you torture it long enough, it'll tell you just about anything you want it to tell you.

I don't think we're torturing risk assessment today, and I think it's been a very useful tool, but I fear that if there's legislative intervention in this area, we may end up doing that. And I'd like to make three basic points.

First of all, that in many circumstances, risk assessment is either not appropriate or not possible, so the approach of requiring it for all regulations would be counterproductive.

Second, that we have to bear in mind that analysis, like anything else, also has diminishing returns. And I suspect, given how overburdened our regulatory agencies are today, we may be approaching the point where imposing additional analytical requirements would have those diminishing returns to a point where it's no longer efficient to do the analysis.

And third, I'd like to conclude by saying I simply don't agree with the notion that there's a danger of massive overregulation of trivial risks today.

First point, there are many circumstances where risk assessment is either not appropriate or not possible. A great deal of the environmental legislation that we have today is precautionary in nature. It's designed to help us prevent harm before harm occurs. In fact, the most successful regulation that EPA has done in recent years, the phaseout of lead in gasoline, was only possible because EPA was allowed initially to regulate the lead content of gasoline, without having to perform a detailed quantitative risk assessment. This regulation ultimately generated enough data that permitted much more sophisticated analyses, which in turn convinced us to phase lead out of gasoline based on the use of cost-benefit analyses.

Second, more analysis, while always theoretically attractive, is not necessarily always more productive. No one's really done a cost-benefit analysis of risk assessment itself or the regulatory analysis process to demonstrate that we don't have enough of it and that we would get more net benefits by increasing the intensity of analysis.

In fact, given that the agencies are already having a very difficult time implementing their statutory responsibilities, I suggest that new analytical requirements actually could be quite counterproductive. Let me give you one example of what happened to OSHA when the Supreme Court imposed a relatively modest set of analytical requirements in the "benzene decision" in 1980.

First, it took OSHA 10 years to promulgate the very regulation at the very level that it had sought to promulgate it in 1977. When it did so, after doing a lot more risk analyses, OSHA concluded that workers had been exposed to extraordinarily high levels of risk during that delay, levels of risk of about 95 in 1,000.

And if you look at the chart over there, it shows that exposure to worksite chemicals is both high on the public's list of priorities—

No. 2—and high among EPA experts. It's clearly a very significant problem. Yet just 2 years ago you had the Eleventh Circuit U.S. Court of Appeals strike down OSHA's quite reasonable attempt to simply update their standards to at least incorporate changes in the voluntary industry consensus standards, which had already gone way beyond what OSHA had been able to do. Most agencies can only do a couple of major regulations a year. Additional risk analysis requirements could be the straw that breaks the camel's back.

Finally, I don't agree that we're in danger of massive overregulation of trivial risks. Someone said this morning that we really haven't seen much benefit from environmental regulation. I challenge anyone to go to Eastern Europe and see what happened to a society that did not have adequate environmental regulations in place. You would see how much benefit we've gotten from those regulations.

It's always easy to come up with an anecdote to show statistically that something looks like massive overregulation. The favorite example of OMB is always the wood preserver regulation, which they claim cost trillions of dollars per life saved. Let me just mention a couple of things about that, though.

First, the regulation never went into effect in the form considered by OMB. In fact, it was substantially modified at the behest of industry, and the wood preservers were relatively happy with the ultimate result.

But second, why is it that we would go ahead and regulate substances like that? I think that the key lies in the findings of EPA's studies of comparative risk assessment. These studies found that the agency's priorities are more in line with those of the public than with those of experts who based their estimates primarily on cancer risks. Why? Perhaps because the public has a lot of other reasons to be concerned about some of these risks.

They're not just concerned about cancer risks. They're also concerned about what happens to a neighborhood economically when there's contaminated dirt there that kids may come in contact with, whether or not we can predict that it's safe to eat such dirt for a certain number of days. They're concerned about the involuntary character of risks. They find it particularly offensive that they should be exposed to toxic substances without their knowledge or consent.

That indeed is the democratic process at work. We should be doing a better job of risk communication and having a dialog with the public, but we should not be intervening at this point to impose an additional set of analytical requirements on agencies that's going to make it more difficult for them to discharge their responsibilities to protect public health.

[The prepared statement of Dr. Percival follows:]

Testimony of

ROBERT V. PERCIVAL

Before the Joint Hearing of
the Subcommittee on
Environment, Energy and Natural Resources and
the Subcommittee on Legislation and National Security
of the Committee on Government Operations,
U.S. House of Representatives

on

RISK ASSESSMENT AND THE MISSION OF THE ENVIRONMENTAL PROTECTION AGENCY

February 1, 1994

RISK ASSESSMENT AND THE MISSION OF EPA

Testimony of ROBERT V. PERCIVAL

February 1, 1994

My name is Robert V. Percival. I am an associate professor of law, the Robert Stanton Scholar, and the director of the Environmental Law Program at the University of Maryland School of Law. Thank you for inviting me to testify at this hearing.

I. INTRODUCTION

Risk assessment has become a highly important, but often poorly understood, tool for informing regulatory decisionmaking. The use of risk assessment is now widely accepted, but considerable controversy remains over how risk assessments are performed and how they should be used by EPA and other federal regulatory agencies. But legislation specifying particular risk assessment procedures or imposing additional analytical requirements on agencies issuing regulations[1] is not an appropriate response to such concerns. Such legislation would actually jeopardize the chances for realizing the promise of risk assessment by asking too much of it at the very time when its value and proper limits are just beginning to be widely appreciated.

Rather than improving the quality of regulatory decisionmaking, risk assessment legislation could further skew regulatory priorities toward a focus on readily quantifiable risks while generating gridlock at already hopelessly overburdened agencies. Unless

[1] See, e.g., the Johnston amendment to the Senate bill elevating EPA to cabinet status. Cong. Rec. April 29, 1993, S 5131 (daily ed.).

implemented in an essentially trivial manner, such requirements would be a prescription for paralysis by analysis that could only further erode public confidence in the ability of government to implement the ambitious promises of the environmental statutes. This would be particularly unfortunate at a time when the Clinton administration has recognized the need to streamline government to make it more flexible and more effective,[2] to make regulatory analysis more selective in its focus,[3] and to give greater attention to the distribution of environmental risks across society.

This testimony begins by reviewing the legal and practical difficulties raised by proposed risk assessment legislation. It emphasizes the inevitable policy judgments that regulatory agencies must make in the face of uncertainty and why regulation to protect human health and the environment is properly precautionary in nature. The testimony then discuss criticisms of how risk assessment is currently used by EPA and other regulatory agencies and explores why there is no reason to believe that risk assessment is systematically biased in favor of overregulation.

II. THE RISKS OF RISK ASSESSMENT LEGISLATION

A. Conflicts with Underlying Statutory Standards

Legislation mandating changes in risk assessment procedures or imposing new analytical requirements on agencies implementing regulatory legislation would create a host of difficult

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[2] See Vice President's National Performance Review (1993).

[3] Executive Order 12866, 58 Fed. Reg. 51735 (Sept. 30, 1993).

legal and practical problems. In recognition of the diverse circumstances in which environmental risks arise, Congress has adopted a wide variety of approaches to regulation that vary substantive and procedural requirements depending upon the nature of the risks to be regulated and the context in which they arise. Some statutes (such as the Toxic Substances Control Act and the Federal Insecticide, Fungicide and Rodenticide Act) require that regulators balance the threat to public health against the cost of regulation when setting regulatory standards. Others (such as the Occupational Safety and Health Act) direct that threats to health be regulated as stringently as is feasible. Another approach (which is embodied in section 112 of the Clean Air Act and the Delaney Clauses of the Food Drug and Cosmetic Act) is to require that standards be based exclusively on concerns for protecting public health (health-based statutes).

While proposals like the Johnston amendment purport not to modify underlying statutory standards, they inevitably would create conflicts between existing statutory directives and the vague, new analytical and substantive requirements they would impose. Efforts to mandate detailed risk assessments or to require that all regulations satisfy some kind cost-benefit standard inevitably would generate conflicts with underlying statutory standards. Agencies would face a quandary in considering how to reconcile divergent substantive and procedural directives. Rather than solving this quandary, provisions stating that such legislation is not subject to judicial review would only compound the problem, while raising the specter that agencies could refuse to implement regulatory legislation on grounds insulated from judicial review.

Much of federal environmental legislation is founded on the notion that agencies should

act to prevent harm even in the face of considerable scientific uncertainty. Thus, precautionary regulation has been repeatedly upheld even in circumstances when it is not possible to perform risk assessments with precision.[4] Mandatory risk assessment requirements could jeopardize the ability of agencies to implement statutory directives to protect the public in the face of scientific uncertainty.

This is illustrated by the history of one of the most successful environmental regulations -- EPA's phaseout of lead additives in gasoline. This phaseout was possible only because the EPA Administrator initially acted in the face of considerable scientific uncertainty to limit the lead content of gasoline. Even though EPA was unable to perform a quantitative risk assessment, the administrator concluded that lead in gasoline presented "a substantial risk of harm," and on that basis ordered reductions in the lead content of gasoline. This was upheld by a court that recognized that "rigorous step-by-step proof of cause and effect . . .may be impossible to obtain if the precautionary purpose of the statute is to be served." Ethyl Corp. v. EPA, 541 F. 2d 1 (D.C. Cir. 1976). These initial regulations ultimately generated data demonstrating the close link between gasoline lead emissions and lead levels in children's blood that helped persuade EPA virtually to eliminate lead additives from gasoline.

For some kinds of regulation risk assessments cannot be performed because the very purpose of a regulation is to gather information about potential risks. Courts have upheld such regulations even in cases where human exposure to a substance is extremely limited

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[4] See, e.g., Reserve Mining Co. v. EPA, 514 F.2d 492 (8th Cir. 1975) (en banc); Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir. 1976) (en banc).

because of the potentially serious harm that toxic substances can cause.[5] A requirement that risk assessment be conducted before test rules are issued could seriously jeopardize EPA's ability to gather data essential for performing risk assessments.

B. Regulatory Paralysis by Analysis

Analytical requirements always have substantial theoretical appeal. After all, who can oppose the notion that regulatory decisions should be based on consideration of the highest quality information available? Yet the principle of diminishing returns applies to information-gathering and analytical requirements as well. At some point the expense and delay occasioned by gathering and considering additional information is more costly than the value of the additional analysis In light of the enormous informational and analytic demands placed on agencies by statute, internal agency procedures, executive oversight, and the courts, proponents of additional analytical requirements face a heavy burden of justification.

EPA and other agencies have had a disappointing track record in implementing environmental, health and safety legislation. The complex judgments required by these regulatory statutes and the sheer volume of the responsibilities delegated to the agencies has strained limited agency resources. Thus, it is not surprising that only a handful of toxic substances have been regulated by EPA under TSCA and the Clean Air Act, while the Occupational Safety and Health Administration has fallen hopelessly far behind in the task of updating occupational exposure standards. Budget constraints, coupled with frequent turnover

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[5] Chemical Manufacturers Assn. v. EPA, 859 F.2d 977 (D.C. Cir. 1988).

of technical staff, and the difficulty of obtaining information that is more readily available to the regulated community than to the regulators, make it extremely difficult for agencies to complete significant numbers of major rulemakings in any given year. As a result of these and other constraints, "[n]o health and safety agency has been able to promulgate regulations for more than three controversial chemicals in any given year."[6]

As Congress continues to expand the regulatory responsibilities of agencies, the need for agencies to develop more efficient rulemaking procedures is growing more urgent. For example, the Clean Air Act Amendments of 1990 required EPA to conduct an order of magnitude more major rulemakings than the agency typically has conducted. The Amendments imposed statutory deadlines on virtually every significant regulatory action they required EPA to take. Despite having announced elaborate plans for adhering to this schedule, by February 1992 EPA had missed 19 deadlines for significant rulemaking actions covering most of the Act's key regulatory programs. For 11 of these missed deadlines, EPA had been unable to meet even its own revised timetable, presented to Congress only three months earlier.[7] By superimposing additional analytical requirements before regulations can be issued, risk assessment legislation would only compound regulatory gridlock.

What is more urgently needed that risk assessment legislation is authorization for

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[6] Shapiro and McGarity, Reorienting OSHA: Regulatory Alternatives and Legislative Reform, 6 Yale J. on Reg. 1, 3 (1989).

[7] Subcomm. on Health and the Environment, House Comm. on Energy & Commerce, Clean Air Left in the Lurch 2-3 (1992).

agencies to adopt new procedures to address the glacial progress of standard-setting. One approach would be to permit agencies to adopt interim standards based on substantially reduced information thresholds while the agency gathers the necessary data to determine at what levels final standards should be set. When OSHA was created, Congress realized that the Agency faced a mammoth task in promulgating regulations to protect workers from exposure to a plethora of workplace hazards. To ensure that workers rapidly were provided with at least a modicum of protection, Congress directed OSHA to adopt as interim standards, without conducting rulemaking under the Administrative Procedure Act, national consensus standards already established by a national standard-setting organization or any health or safety standards already adopted by other federal agencies. In 1971 OSHA adopted exposure limits for approximately 400 chemicals based largely on the Threshold Limit Values (TLVs) adopted by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1968.

Although Congress contemplated that OSHA would revise the interim standards to provide more protection to workers through normal rulemaking proceedings, OSHA did not attempt to revise the standards to keep them up to date with changes in the ACGIH TLVs until 1989, long after the TLVs had been lowered for hundreds of the chemicals. Yet OSHA's efforts to use a generic rulemaking simply to update the standards to reflect changes made by the ACGIH were struck down in court, even though the agency estimated that the revisions would prevent 55,000 occupational illnesses and 683 deaths annually.[8]

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[8] AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir. 1992).

OSHA's difficulties are largely a product of the relatively modest analytical requirements imposed on the agency by the Supreme Court's decision in what is known as the *Benzene* case.[9] In that case a bare plurality of the Court rejected OSHA's effort to lower the permissible exposure limit to benzene because OSHA had not performed a risk assessment demonstrating that the significant risks to workers would be appreciably reduced. In the years that followed this decision, OSHA conducted five risk assessments that confirmed its original conclusion that benzene posed extremely serious risks to workers. The risk assessments indicated that workers exposed to benzene at the level permitted by the existing standard faced excess leukemia risks ranging from 44 to 152 per 1,000. In 1987, OSHA finally adopted the very exposure limit struck down by the Supreme Court. OSHA concluded that exposure to 10 ppm of benzene posed a risk of 95 additional leukemia deaths per 1,000 workers, a level greatly in excess of both other toxic substance risks OSHA had deemed significant (including arsenic, ethylene oxide, and ethylene dibromide) and the risk of accidental death in high- and average-risk industries (where death risks ranged from 30 to 3 in 1,000). OSHA estimated that the new PEL would prevent at least 326 deaths from leukemia and other blood diseases and that the actual number of deaths prevented would be considerably greater.

Thus, due to judicial intervention, it took more than ten years for OSHA to lower the benzene standard to the very level the Agency had sought to adopt on an emergency basis in May 1977. This illustrates that the imposition of additional analytical requirements can have

[9] Industrial Union Dept., AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980).

its own serious costs, by delaying necessary regulation that could have prevented the exposure of thousands of workers to benzene risks estimated to cause scores of additional deaths.

This is not to suggest that risk assessment should be abandoned, but rather that it should employed in a genuine effort to improve the quality of regulation, rather than as a disguised tool for creating regulatory gridlock. If we do not require industrial dischargers to publish detailed risk assessments prior to exposing the public to any type of pollutant, why should we insist that all efforts to protect the public from such exposures be halted until regulators have done so? President Clinton's new executive order on Regulatory Planning and Review employs a sensible approach by recognizing that regulatory analysis will be most useful if applied in a selective fashion.[10] The executive order directs agencies to "consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction," as a means for setting regulatory priorities. But it does not require that risk assessments be conducted before any regulations can be issued. Rather than requiring that all EPA regulations be submitted to OMB for review, the thrust of the new executive order is to require such review only for the most significant regulatory initiatives. If implemented in a sensible fashion, these procedures should be adequate to insure reasoned decisionmaking by regulatory agencies.

The Clinton administration's approach to regulatory review is a refreshing change from the policies that prevailed during the Reagan and Bush administrations. Under the previous

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[10] Executive Order No. 12866, 58 Fed. Re. 51735 (Sept. 30, 1993).

Executive Order 12291, the regulatory review process was used to displace agency decision-making by dictating substantive changes in regulations, often in ways that were inconsistent with statutory standards. By refusing to clear regulations, OMB was able to employ regulatory review to promote less stringent regulation rather than to increase the net benefits of regulation.

C. Comparative Risk Analysis

Proposals to make risk assessment mandatory before regulations can be issued could bias regulatory priorities toward more readily quantifiable risks that may not be as serious as other problems. This could exacerbate a problem that already has been acknowledged as many scientists believe that far more emphasis has been placed on controlling cancer risks than on regulating other environmental health risks. This may be a product of the fact that risk assessment techniques are better developed for cancer than for neurological, reproductive, or developmental risks. While regulators often assume that regulations to protect against cancer will also protect against other health risks, scientists are now beginning to question the accuracy of such assumptions.[11]

This would be a particularly unfortunate result of risk assessment legislation since EPA already is acting in a sensible manner to improve its ability to use risk assessment as a priority-setting tool. In 1987 EPA embarked on a major initiative to examine the consequences of using comparative risk assessment as the central principle to govern agency priority-setting. The agency's report, entitled *Unfinished Business: A Comparative*

[11] See, e.g., Gibbons, Reproductive Toxicity: Regs Slow to Change, 254 Science 25 (1991).

Assessment of Environmental Problems, found that it was virtually impossible to perform any rigorous quantitative assessments of risks other than cancer. While it attempted to provide rough qualitative rankings of cancer, non-cancer health effects, ecological risks and risks of economic damage, EPA found that data were simply inadequate to perform rigorous risk assessments of most existing problems and that even rough rank-orderings were virtually impossible for new activities such as biotechnology and new toxic chemicals. The study found serious conceptual difficulties in comparing risks that are fundamentally different in character (e.g., comparing ecological risks to risks of cancer or risks of damage to developmental, immunological, reproductive, or respiratory systems) and that environmental exposure data were surprisingly poor. Despite all these difficulties, the *Unfinished Business* report found that "EPA's priorities appear more closely aligned with public opinion" than with the results of its risk assessments.

In a followup report, entitled *Reducing Risk: Setting Priorities and Strategies for Environmental Protection* (1990), EPA's Science Advisory Board enthusiastically endorsed the notion that the agency should use environmental risk as a priority-setting mechanism. But they also acknowledged the difficulties involved in performing comparative assessments of environmental risks. The SAB found that even defining categories of environmental problems was fraught with difficulty. They noted that the categories employed in *Unfinished Business* grouped some problems on the basis of the types of pollution involved, others on the basis of sources of pollutants, and others on the basis of receptors of pollutants. The SAB deemed this to be unsatisfactory for purposes of comparative risk assessment because the categories lacked a consistent basis for comparison. They also noted that *Unfinished Business* omitted

some very serious problems such as habitat destruction and the decline in genetic diversity. The SAB emphasized that the rankings produced by *Unfinished Business* in many cases were subjective and "cannot be supported fully by existing data" in large part because of the absence of good data to assess certain risks. Moreover, they questioned some of the assumptions and conclusions made in the prior report.

After independently reviewing data on relative risks, the SAB generally agreed with the most striking finding of *Unfinished Business*: that regulatory priorities are more closely aligned with the public's perception of risks than with the experts'. They concluded that "the remaining and emerging environmental risks considered most serious by the general public today are different from those considered most serious by the technical professionals charged with reducing environmental risks."[12] For example, the *Reducing Risk* task force concluded that ecological risks were not getting the attention they deserved and that EPA should consider them to be as important as human health risks because ecosystems are essential to human health and long-term economic growth and "are intrinsically valuable in their own right."

Reducing Risk endorsed the notion that "EPA should target its environmental protection efforts on the basis of opportunities for the greatest risk reduction." It recommended that EPA incorporate risk-based priorities into the Agency's strategic planning and budget processes while making efforts to improve data and analytical methodologies to support comparative risk assessment. In contrast to this sensible approach to the use of comparative

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[12] EPA Science Advisory Board, Reducing Risk 12 (1990).

risk assessment, legislation mandating that EPA publish comparative risk analyses as a precondition for issuing any regulation does not offer much hope for improving regulatory priorities. Rather, it would simply demand of EPA what is likely to be impossible in most circumstances and contribute further to regulatory gridlock.

III. CRITICISMS OF RISK ASSESSMENT

While environmentalists initially attacked risk assessment out of concern that it would bias regulatory decisions in a manner detrimental to environmental protection, they now have become comfortable with risk assessment. Ironically, risk assessment is now more frequently coming under attack from the regulated community, particularly when it is used to support environmental regulation. Industries facing more stringent regulations are now seeking to revisit assumptions or methodologies employed in the risk assessments used by regulators.[13] Scientists are being asked to take a second look at the risks of substances long ago deemed extremely hazardous based on new and supposedly more refined data.[14]

A. Risk Assessment Procedures Are Not Inherently "Too Conservative"

The regulated community's most consistent criticism of risk assessment is the notion that it employs assumptions that are too conservative, resulting in unreasonably stringent regulation. These criticisms fail to take into account the many factors may cause risk

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[13] See, e.g., Roberts, Dioxin Risks Revisited, 251 Science 624 (1991); Roberts, Flap Erupts Over Dioxin Meeting, 251 Science 866 (1991).

[14] Abelson, Excessive Fear of PCBs, 253 Science 361 (1991); Stone, No Meeting of Minds on Asbestos, 254 Science 928 (1991).

assessments to seriously underestimate actual risks. Most risk assessments do not consider all exposure pathways, all hazard endpoints, or the possible synergistic effects of the multiple pollutants to which humans are exposed. Some human subpopulations may be more sensitive to the toxic effects of certain substances than the animal species typically tested in bioassays.[15]

The notion that risk assessment is inherently too cautious also has been contradicted in several instances by discoveries that certain substances pose substantially greater risks than originally thought. For example, scientists' definition of lead poisoning has been ratcheted downward substantially over the last two decades as new information has revealed that levels previously thought to be safe posed significant risks to health. Moreover, because individual variability in susceptibility to risks is high, if risks associated with chemical exposure are relative, rather than simply additive, as data suggest for radiation-induced tumors,[16] then susceptible individuals face much greater additional risks from chemical exposure than are reflected in current risk assessments.[17]

Conservative assumptions actually are more frequently used to justify decisions not to

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[15] See Center for Risk Analysis, Comments on OMB, Current Regulatory Issues in Risk Assessment and Management (Dec. 17, 1990).

[16] Storer, Mitchell, and Mitchell, Extrapolation of the Relative Risk of Radiogenic Neoplasms Across Mouse Strains to Man, 114 Radiation Res. 331 (1988).

[17] Hoel, A Balanced Approach to Risk Assessment, 7 Toxicology & Indus. Health 305, 310 (1991).

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regulate because they increase the decisionmaker's confidence that the risks are no greater than a certain level.[18] By contrast, EPA at times has eschewed a conservative approach to risk assessment in an effort to demonstrate that risks were at least as great as the threshold level needed to justify regulation. For example, when EPA considered whether to phaseout remaining uses of asbestos, the agency deliberately chose to focus only on the most easily quantifiable risks.[19] Even though EPA believed that its quantitative risk assessment substantially underestimated the true risks of continued asbestos use, perhaps by an order of magnitude, it thought that it could demonstrate that the risk warranted regulation. However, this regulation was struck down by the Fifth Circuit in the *Corrosion Proof Fittings* decision, which focused only on the risks EPA chose to quantify, disagregated them on a product-by-product basis, and faulted the agency for failing to provide detailed assessments of the costs and benefits of less stringent alternatives.[20] The *Corrosion Proof Fittings* decision illustrates how extraordinary the barriers to regulation are today when a substance that is the paradigmatic candidate for a TSCA product ban cannot be phased out.

Because of pervasive uncertainty, some form of default assumptions must be employed when quantitative risk assessments are performed. EPA has properly sought to employ

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[18] Ruckelshaus, Risk in a Free Society, 14 Envtl. L. Rep. 10190, 10191 (1984).

[19] 54 Fed. Reg. 29,460 (1990).

[20] Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).

assumptions that reflect the mainstream of scientific thinking while recognizing the need to make regulatory judgments in the face of limited data and scientific uncertainty. This is reflected in the conclusions of the recent National Academy of Sciences report, *Science and Judgment in Risk Assessment*, which finds that EPA's general approach to risk assessment is sound, while recommending measures to improve its effectiveness.[21] Even those with legitimate questions concerning the appropriateness of certain assumptions employed in risk assessment should be wary of advocating legislation that would place Congress in the position of dictating what is or is not "good science" in this rapidly developing field.

B. Regulation Generally Has Not Focused on Trivial Risks

Advocates of risk assessment legislation argue that it is necessary because regulation has spent inordinate amounts of societal resources in responding to what often are trivial risks. The suggestion that environmental and health risks are massively overregulated ignores the great difficulty that regulatory agencies have had in discharging even their most basic responsibilities. Most complaints about regulation of trivial risks either involve the cost of remediating environmental contamination after it has occurred, risks that have trivial benefits, or risks whose involuntary character renders them particularly offensive to the public. The extreme cost of cleaning up environmental contamination not only reflects the primitive state of remediation technology, but it also counsels in favor of making greater efforts to prevent environmental releases before they occur. While the color additives Delaney Clause may prevent extremely weak carcinogens from being used in food coloring,

[21] National Research Council, Science and Judgment in Risk Assessment (1994).

Congress could quite properly make its own risk assessment that the benefits of color additives are unlikely to be substantial enough to warrant the expense of individualized risk assessment. The fact that people voluntarily incur risks substantially greater than those that are the subject of environmental regulation, does not indicate that they are irrational, as discussed below.

Individuals are willing to accept greater degrees of risk for risks that they can choose to avoid (voluntary risks) than for risks that they have little or no choice about (involuntary risks). Some studies suggest that people perceive widely dispersed risks as less risky than highly concentrated risks, even though the total population risk in both cases is identical. A chance that 1 person will die in each of 100 neighborhoods, each with 100 inhabitants, is perceived as a more acceptable risk than the same chance that one of the neighborhoods will be wiped out entirely, the other 99 remaining untouched. Based on the persistent findings of cognitive psychologists that these and other distinctions matter to people, Peter Sandman defines risk as"the sum of hazard and outrage." He notes that there is voluminous data indicating that voluntariness, control, and fairness are important components of how the public assesses the acceptability of risk. Sandman questions whose behavior is irrational -- the public or the risk manager who "continues to ignore these factors --- and continues to be surprised by the public's response of outrage."[22]

It is important to bear in mind that risk assessment is not a black box that should be insulated from public scrutiny. Even if risk management decisions cannot routinely be made

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[22] P. Sandman, Risk Communication: Facing Public Outrage, EPA J. 21-22 (Nov. 1987).

by plebiscite, the perception of trustworthiness in regulatory agencies may be as important to the public's acceptance of such decisions as are risk assessments. " 'Tolerable' risk level issues are inextricably linked with the process by which the risk was allocated or imposed."[23] Maintaining public trust appears to require that agencies organize themselves so that the public and interested parties can communicate their concerns, assumptions, and choices and that ultimate decisions be seen in some sense as responsive to those inputs.[24]

The richer, the more multi-factored our perceptions of risk, the more difficult becomes the exercise of comparing risks to one another. If more than one risk characteristic is acknowledged to be germane to policy formation, for example, then the construction of simple one-factor rankings of the kind that are frequently used by critics of current regulatory priorities becomes misleading. Efforts to impose additional analytic preconditions on regulation fail to address how regulatory authorities should deal with these and other legitimate public concerns that can warrant regulatory action even when risk assessments suggest that overall population risk is quite low.[25]

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[23] Kasperson, Six Propositions on Public Participation and Their Relevance for Risk Communication, 6 Risk Analysis 275, 280 (Sept. 1986).

[24] See, e.g., Fiorino, Environmental Risk and Democratic Process: A Critical Review, 14 Colum. J. Envtl. L. 501 (1989); McGarity, Risk and Trust: The Role of Regulatory Agencies, 14 Envtl. L. Rptr. 10198 (Aug. 1986)

[25] See Raynor and Canoter, How Fair Is Fair Enough? The Cultural Approach to Societal Technology Choice, 7 Risk Analysis 3 (Mar. 1987).

IV. CONCLUSION

While there are ample reasons for reinventing regulation, proposals to mandate risk assessment before environmental regulations can be issued are the wrong solution for the wrong problem at precisely the wrong time. Such legislation would create a host of legal and practical difficulties that would contribute to regulatory gridlock at the very time when the Clinton administration has taken major steps to improve the quality of regulatory analysis. A better approach would be to bolster the capability of agencies to perform regulatory analysis while making it easier to revise and update regulatory standards.

Mr. SYNAR. Thank you, Professor. Dr. Graham.

STATEMENT OF JOHN D. GRAHAM, Ph.D., DIRECTOR, CENTER FOR RISK ANALYSIS, HARVARD SCHOOL OF PUBLIC HEALTH

Dr. GRAHAM. John Graham, director, Harvard University Center for Risk Analysis.

The question before us today: what should Congress, if anything, do about risk analysis? My answer to that question will come in the form of the advice that I would provide to my students, students who are studying risk analysis at the Harvard School of Public Health.

If they had a job offer to go to Congress to work with, say, Senator Johnston, Senator Moynihan, Congressman Synar, to work on risk analysis for a couple of years, I would advise them to do so. If they had an offer to go to work for Sally Katzen on developing a concept like Judge Breyer talked about, and begin a career in that field, I would advise them to do that.

The sad thing is if they came and said, "I'm going to go to work for EPA. Do you think that's a good idea, now, to go to work for EPA?" I would be very reluctant to say yes to that. I want you to think about that for a little bit because that is the problem we are in in risk analysis.

This week's issue of Science Magazine—if you haven't read it, I strongly encourage you to do so. The title of the article, "Can Carol Browner Reform EPA? One year after becoming EPA Administrator, Browner has a lot to do to fulfill her promise to make science the centerpiece of environmental regulation."

The problem is there's a lack of commitment at the leadership level of the Environmental Protection Agency to the field of risk analysis, and that, I think, is something that Congress can make a difference on.

What are the specifics? I would recommend, as a starting point, saying to the Congress, "We're going to have a new, high-level Office of Risk Analysis within the Environmental Protection Agency that will report directly to Carol Browner and will be of continuing interest to members of Congress, to Senators." You won't just pass this law, create an Office of Risk Analysis and then walk away. You will care to see to it that it's implemented over time and that there are, in fact, careers for students like mine to develop in the Environmental Protection Agency.

There are detailed comments. I've got 10 single spaced, typed pages, lots of comments on specific bills. You can make a difference. My colleagues are right. You can be too prescriptive, but we've got to get some heat on EPA to get serious about risk analysis. Thank you.

[The prepared statement of Dr. Graham follows:]

TESTIMONY OF
JOHN D. GRAHAM, Ph.D.

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THE ROLE OF RISK ANALYSIS IN ENVIRONMENTAL PROTECTION

SUBCOMMITTEE ON ENVIRONMENT, ENERGY AND NATURAL RESOURCES
SUBCOMMITTEE ON LEGISLATION AND NATIONAL SECURITY
Committee on Government Operations
United States House of Representatives
Washington, D.C.

February 1, 1994

My name is John D. Graham. I am Professor of Policy and Decision Sciences at the Harvard School of Public Health and Director of the Harvard University Center for Risk Analysis. Before beginning my testimony, I would like to thank my colleagues at the Center, especially March Sadowitz, for their help in preparing this testimony. Of course, the views expressed here are mine and should not be attributed to Harvard University.

Chairman Conyers, Subcommittee Chairman Synars, and Members of the Committee, thank you for the opportunity to speak today on the central role that risk analysis should and does play in environmental policy. Since I trust that there is widespread consensus that EPA should be elevated to Cabinet status, an opinion that I certainly share, I would like to focus on why the new Department should base its policies and regulations on risk analysis.[1] Before discussing legislative details, it is useful to remind ourselves why we are here today.

Statement of the Problem

The American people are being bombarded with new information about potential dangers to their health, safety and natural environment. What are citizens to make of the potential dangers from pesticide residues on food, radon in the basements of our homes, electric and magnetic fields from powerlines, deteriorating lead paint in old houses, and global warming?

Which of these dangers are real? Which ones have been exaggerated and which may have been understated? Which risks are serious enough to worry about, and how can we reduce them through cost-effective actions? We are here today because the American people want answers to these kinds of questions.

Let me suggest that the answers, to the extent they can be found, will come from a relatively new interdisciplinary field of study called risk analysis. At the Harvard Center for Risk Analysis, we are dedicated to advancing the field of risk analysis through training of students, scientific research, and communication with policy makers and the public. While some people have suggested that risk analysis is arcane, undemocratic and even tyrannical, we disagree. The Center has found in random digit-dial surveys of the population that a large majority of Americans support not only elevation of EPA to Cabinet status but the use of risk analysis to allocate wisely our scarce resources for environmental protection.[2]

Everyone in this hearing room recognizes that resources are scarce and we cannot possibly eliminate every risk. While citizens want more environmental protection, they also want more transportation, more civil rights, more health care, more education, more child care, more and safer consumer products, more

police protection, and the list is endless. The scarce resources we spend on environmental protection are in fact resources that cannot be used to pursue these other worthy social goals.

The EPA has estimated that Americans will soon be spending over $150 billion each year on environmental protection, a claim on scarce resources that is increasing much faster than the growth rate of the economy as a whole.[3] As Senator Moynihan has noted so eloquently, this is not necessarily too much to spend for clean air and water but it is certainly too much to invest unwisely.[4] When our nation squanders scarce resources on low-risk problems, we miss the opportunity to save lives and protect ecosystems from high-risk dangers. When voters sense that environmental programs are too extravagant, they reject them. They did so at the polls in California and New York in 1991, and in Ohio and Massachusetts in 1992, where environmental ballot initiatives were rejected.[5] I would add that all three of these initiatives neglected the crucial role of risk analysis in setting priorities for environmental protection.

Risk Analysis is Part of the Solution

In the scientific community, there is broad support for the use of risk analysis to help policy makers allocate scarce resources.[6] Although some environmental and industry groups have expressed doubts about the government's growing use of risk analysis, many of the biggest success stories in the history of EPA, such as the phase-out of lead in gasoline, have been stimulated and informed by the results of careful risk analysis.[7] A recent report from the National Academy of Sciences has encouraged the EPA to continue to use risk analysis to help reduce pollution under the Clean Air Act. The NAS report also contains some excellent recommendations aimed at correcting weaknesses in the way EPA currently conducts risk assessments and reports results to the public.[8]

As important as risk analysis is, it cannot be the complete solution to the challenge of managing risks. Value judgements must be made about how much risk reduction is affordable, how much weight will be given to the welfare of future versus current generations, how much weight will be given to the welfare of people versus the welfare of ecosystems, and how much concern will be expressed for risks that are perceived to be voluntary as opposed to those that are perceived as involuntary. While risk analysts have useful tools to illustrate the implications of differing value judgements, in the final analysis it is the American people, led by policy makers, that must make the ultimate value judgements.[9]

Initiatives by EPA and the Clinton Administration

Since Bill Ruckelshaus returned to Washington to rescue EPA

from scandal in 1983, the Agency has made slow but steady progress toward a risk-based approach to environmental policy. Both Lee Thomas and Bill Reilly deserve substantial credit for advancing the cause of risk analysis at EPA.[10] Use of analytic methods is especially important in a field such as environmental policy where the science is complex and thoughtful consideration of value tradeoffs is required.[11]

Despite the Agency's record of progress, I am very concerned about the future of risk analysis at EPA. This week's issue of the journal Science contains a sobering article (attached) which reveals the ambivalence of current EPA management toward risk analysis and environmental science as a whole.[12] During the last year, little progress has been made toward revision of the Agency's outmoded cancer risk assessment guidelines. In 1991 the EPA's Risk Assessment Council issued Agency-wide guidance to promote more responsible risk characterizations but little progress has been made toward implementation of this guidance. Some useful work has been performed on the critical role of risk analysis in reform of the Delaney Clause and the Superfund law but the Agency's precise position on these critical issues remains ambiguous. As a close observer of EPA, I have the sense that EPA's leadership is spending more energy discouraging the Congress from passing amendments related to risk analysis than they are making serious Agency-wide initiatives to expand and refine the role of risk analysis in Agency decision making.

Congressman Conyers, I would like to applaud your efforts and the efforts of EPA Administrator Browner to achieve environmental justice in EPA decisions. Environmental inequities deserve much more attention than they have received in the past.[13] At the same time, it should not be forgotten that it will take new and improved applications of science and risk analysis to reveal which inequities in the distribution of environmental risks are most serious and therefore deserve the highest priority. My point is that the supporters of risk analysis and environmental justice should be friends rather than foes.

The Clinton White House has issued an executive order that promotes the role of benefit-cost analysis in regulatory planning. While this order is a useful step in the right direction, it does not do very much to promote or improve the methods of risk assessment per se. I have spoken to White House officials who are interested in promoting the role of comparative risk assessment in the decisions of all federal regulatory agencies. There are good people involved in this effort but it is too early to assess how much progress they will make.

Another theme that we hear from EPA is the emphasis on "pollution prevention." This is a good concept but again it cannot be implemented intelligently without some form of risk analysis. Which pollutants are the most serious and should be given priority

in prevention efforts? If "pollution prevention" policy causes chemical A to be substituted for chemical B in making computers, will that reduce risk to the public and the environment? These questions cannot be answered without risk analysis. Again, my point is that the supporters of pollution prevention and risk analysis should be friends rather than foes.

Guidance for Congress

Regardless of how much this Administration moves to promote risk analysis, it is absolutely critical that Congress embrace risk analysis. Many of the problems of resource misallocation that we face, such as the inefficient expenditures made under the Superfund law, have resulted from the imperfect laws passed by Congress. If Congress does not pass legislation to promote risk analysis, it will be a signal to EPA that return to "business as usual" is appropriate. Since there are many proposals on Capitol Hill, let me be explicit about what makes sense and what does not make sense.

The new Department should have a broad-based Office of Risk Analysis as proposed by Congressman Zimmer. The responsibilities of that Office should include (1) assurance that each rulemaking is accompanied, where feasible, by a formal risk analysis as described in Senator Johnston's amendment to the EPA Cabinet bill, (2) guidance on the technical aspects of risk assessment as described in the recent NAS report, (3) guidance on communication of risk to the public along the lines suggested by Congressmen Brown and Moorehead (especially the reporting of uncertainty through central estimates of risk as well as plausible upper and lower bounds on risk), and (4) periodic ranking of risks for priority setting as practiced in EPA's Unfinished Business report and recommended by Senator Moynihan's bill. If Congress were to pass such legislation, in conjunction with efforts to promote environmental justice and pollution prevention, the nation will have taken a very serious step in the right direction.

I also believe that risk analysis legislation that covers all federal agencies is urgently needed, especially if the solution proposed by Judge Breyer is to achieve permanence in the Executive Office of the President.[14] My personal viewpoint is that risk analysis expertise in the Executive Office of the President should be expanded in the Office of Science and Technology Policy with close collaborative links to the economists in the Office of Management and Budget and the Council of Economic Advisors.

In conclusion, let me offer a provocative illustration of what Congress should not do in the area of risk analysis. There are some interest groups that have suggested that all involuntary cancer risks in daily life should be reduced to less than one chance in a million lifetimes, regardless of how much that costs to achieve or what products or jobs will be lost in the process.[15] Now, I want to remind everyone here today that there is tiny but

nonzero chance that an airplane headed for National Airport will veer off course, strike Capitol Hill, and knock off several Members of Congress and their staff. I don't know this exact probability, but we all face this kind of involuntary risk every day of our lives.

Based on actuarial science, it has been estimated that a baby born today, given current mortality rates, has not one chance but four chances in a million of being killed on the ground by a crashing airplane.[16] While we certainly have regulated airplanes to minimize this probability, noone has seriously suggested that we should ban all airplanes that fail a one-in-a-million test, without even considering the benefits provided by airplanes to travelers or the impacts on the national economy. All technologies in life ranging from airplanes to electric power lines are associated with benefits and risks (many of which are involuntary). Instead of fixating on specific risk cutoffs, we need to carefully weigh the risks and benefits of each technology and the possible alternatives to that technology.[17]

It is certainly true that risk analysis takes time and money. The amount of this investment is very small compared to the stakes we are talking about in regulating environmental risks. I certainly would oppose a Cadillac version of risk analysis when something less complex can do the job. Indeed, I am fond of telling my students that the most useful risk analyses are often those that focus on the most critical factors using a small number of calculations on a portable calculator. I think most Americans think this way as well.

Thank you for the opportunity to testify today.

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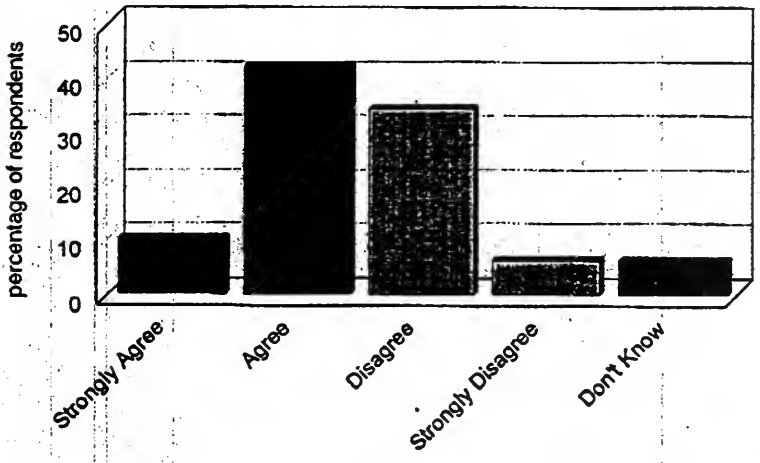
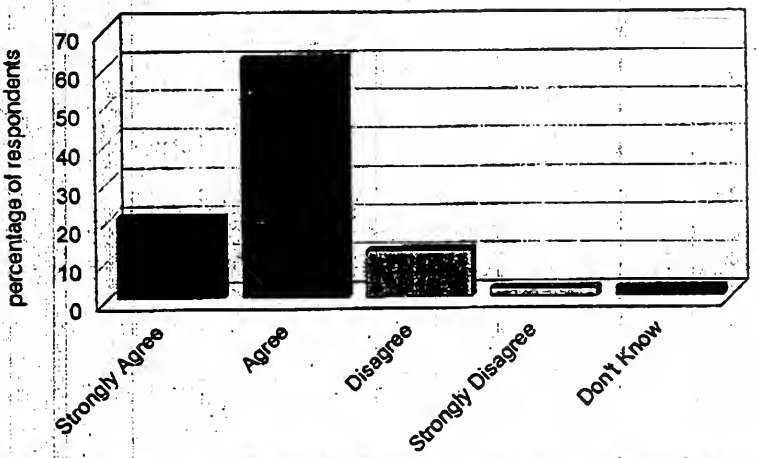
Question: The job of Administrator of the U.S. Environmental Protection Agency should be promoted to Cabinet status in the White House?



Question: The government should use risk analysis to identify the most serious environmental problems and give them the highest priority in environmental spending decisions?



a. Percent numbers may not add to 100 due to non-responses and rounding to whole numbers.

Can Carol Browner Reform EPA ?

One year after becoming EPA administrator, Browner has a lot to do to fulfill her promise to make science the centerpiece of environmental regulation

On 22 November last year, Carol Browner, administrator of the Environmental Protection Agency (EPA), gave her troops a pep talk. Standing with her top aides on a podium outside EPA headquarters, Browner complimented her staff, laid out her agenda, and exhorted everyone "to employ the best possible science" in making regulatory decisions for the $6.6 billion agency. The scientists applauded her words that balmy fall day, but for them, the lineup sent a less positive message. The agency's science adviser wasn't on the rostrum—he apparently didn't rank as a top aide—and conspicuously absent was a permanent head of the Office of Research and Development (ORD), the agency's main research arm. Almost a year after Browner took office, she has yet to find a prominent outside scientist who's willing to take the job.

Environmental scientists say the gaps in that lineup are a small but telling reminder of how hard it will be for Browner to achieve her goal of putting science at the heart of EPA decision making. It's not for lack of trying: In a recent interview with *Science*, Browner talked about her plans to improve communications between EPA scientists and regulators, to incorporate scientific issues into the regulatory process at the earliest possible stage, and to solicit opinions from outside scientists and other constituents in a series of public meetings. But she must also deal with a track record that causes scientists to gnash their teeth. "The agency still doesn't have an understanding of science," says Ellen Silbergeld, a University of Maryland toxicologist who closely follows federal environmental policy.

In particular, scientists want the former Florida state environmental official to do a better job incorporating scientific and economic uncertainties into its regulations, and to stop diverting funds from long-term research into short-term projects to support regulatory decisions. "EPA often makes assumptions that, in my view, are not biologically plausible," says toxicologist Bailus Walker, dean of the University of Oklahoma's Health Science Center, who was Browner's choice to head ORD until he withdrew last July (see box, p. 313). Within the agency, says EPA toxicologist Linda Birnbaum, "we'll initiate a major program, then all of a sudden there's no money." Scientists are also unhappy with the lack of progress on implementing some of the recommendations in two reports commissioned by Browner's predecessor, William Reilly, that urged EPA to improve its science and bring its activities more in line with actual environmental risks (see table, p. 314).

RICK MOSKAL

Make way for science. Browner wants "fundamental overhaul" of how EPA uses research.

"It's bizarre," says Rutgers toxicologist Michael Gallo. "For years, we in the environmental science community were extremely worried about the Reagan-Bush approach to things. Now all we talk about is the level of stagnation—no, catatonia—we see in the [Clinton] Administration."

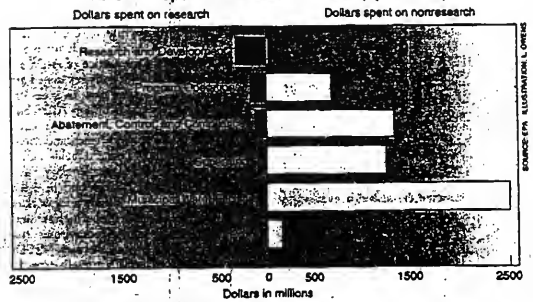
Browner acknowledges these problems and says she understands the frustration of EPA scientists whose basic research projects have been brought to an abrupt halt. "There's no point putting money in a long-term project if you can't put it in for 5 or 6 years," she says. But real change, she says, will require no less than a "fundamental overhaul of how EPA perceives the role science plays in agency decisions."

Research potpourri

Browner will have to change perceptions throughout the agency, for EPA's research enterprise is spread across several offices, each of which has its own mission and its own reasons for supporting research. Estimates of EPA's annual research budget range from $500 million to more than $1 billion, depending on how research is defined (see chart). The lion's share is spent by ORD, which operates a dozen in-house laboratories as well as an extramural program for contractors and academic scientists.

Its work is intended to help EPA carry out its primary role as a regulatory agency, charged with protecting the nation's environment—a role spelled out in such major pieces of legislation as those focusing on clean air, clean water, and the use of pesticides. But, as the agency prepares to mark its 25th anniversary next year, it is facing a growing backlash from environmental policy makers and scientists questioning whether the $115 billion spent each year in the United States on environmental protection reflects the best scientific understanding of environmental and health risks. Cash-strapped local governments, in particular, are challenging the scientific basis of "un-

Where EPA Spends Its Research Dollars (by account)



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Strict Ethical Rules Confound EPA Science

Carol Browner says the hardest scientific problem she's faced in her first year as Environmental Protection Agency (EPA) administrator has been finding a prominent scientist to head the agency's Office of Research and Development (ORD). She thought she had filled the job last February when the White House announced its intention to nominate toxicologist Bailus Walker, dean of the University of Oklahoma's Health Science Center. But Walker withdrew from consideration 5 months later, before the White House sent his nomination to Capitol Hill for approval. Since then, several academic scientists have told EPA they are not interested in the job.

Bailed out. Bailus Walker said no to top research job.

ROBERT RAYCOX

The main problem is the EPA general counsel's strict interpretation of government ethics rules. "The ethics rules fail to take into account the life of an academic scientist," says Browner.

In Walker's case, the stumbling block was a new guideline from the White House that restricts the activities of political appointees after they leave federal service. The rule states that a "senior appointee" must not "lobby any officer or employee of that agency" for 5 years after leaving that agency. To EPA's general counsel, the rule amounts to a 5-year moratorium on seeking EPA grants.

"The 5-year moratorium was one of the most critical factors in my decision" to pull out of the nomination process, Walker says. "I had to think about employment options after federal service." Walker had complained in July about an "inordinately long" vetting process (*Science*, 6 August 1993, p. 671), but he says now that his reference to having "additional time to rethink the ramifications" of taking the job "was really a code word for weighing the pros and cons of the ethics rule."

A second deterrent to recruitment is a rule that precludes federal workers from using their official titles to endorse certain activities. The EPA general counsel's office says this means an ORD chief must immediately sever all ties with ongoing projects, even unpublished research. "There's no problem with polishing up a report," says Gerald Yamada, deputy general counsel, but nominees must refrain from doing "midstream" work. This rule has doomed consideration of several prominent academics, including Frederica Perera, a molecular epidemiologist at Columbia University. "We were writing up studies that have lasted 3 to 5 years," says Perera, who says she was sounded out for the ORD job. "That's a difficult time for any researcher to say, 'I'm going to disconnect from my work.'"

The agency's interpretation of ethics rules affects rank-and-file scientists, too. Last month, for example, ORD held a meeting to develop a research plan to study the health effects of gasoline additives used to reduce smog, inviting scientists from the Centers for Disease Control and Prevention, the state of Alaska (some of whose residents have complained of health problems stemming from use of the additives), and industry. But university scientists and contract researchers were excluded because, as explained in a document obtained by *Science*, "EPA's ethics and extramural funding regulations would prevent them from receiving EPA funds to perform the planned projects."

Other research agencies appear to be taking a less restrictive approach. "The problems EPA appears to be experiencing haven't occurred at NSF [National Science Foundation] to my knowledge," says NSF general counsel Lawrence Rudolph. Even officials at the Food and Drug Administration (FDA), a regulatory agency like EPA, say they haven't experienced similar problems in recruiting top scientists.

For now, EPA's general counsel's office has no plans to alter its interpretation of the ethics rules. "I've been asked to explain the rules, and some people haven't been happy," says Yamada. However, he adds, "No one has asked me to bend the rules." And despite the discomfort caused by the rules, Browner says she has no plans to force him to bend.

–R.S.

funded mandates"—federal environmental regulations that municipalities must pay for. At least one city—Columbus, Ohio—has even formed an environmental science advisory committee that, according to its chairman, chemist Edward Hayes of Ohio State University, "is a source of independent scientific and engineering advice about environmental risks and remedies." The panel hopes to educate EPA about the scientific uncertainties of environmental protection at the regional level.

The public also wants EPA to build its regulations on a more solid scientific foundation. In a survey of 1000 Americans released earlier this month by the Harvard Center for Risk Analysis, 83% agreed "the government should use risk analysis to identify the most serious environmental problems," but only 42% thought "the government does a good job of using science in the development of environmental regulations."

Congress, too, is beginning to pay more attention to EPA science. The House and Senate are considering legislation to add an extra layer of scientific review to EPA's decisions and to compare the costs and benefits of proposed and existing regulations. But that attention isn't entirely benevolent. One of President Clinton's campaign pledges—to raise EPA to Cabinet status—has been stymied by attempts to mandate risk and benefit-cost assessments that might force EPA to use particular scientific analyses even after they become obsolete.

Looking for answers

In response, Browner says her goal is to ensure that "good science is at the foundation of every decision EPA makes," and an Administration official says the president's 1995 budget to be submitted next month will include more money for ORD. But Browner confesses she doesn't have all the answers. "I'm looking to people inside the agency, people who've been here 10, 20 years," says Browner, "and I'm saying to them, 'What do you think is the best way to use our science?'"

One of the biggest complaints Browner is hearing from those veterans is that the agency has failed to design and carry out a sound long-term research agenda. Although they wouldn't mind getting more money, EPA scientists are more troubled by the agency's ever-changing research priorities. "We constantly have to justify and rejustify what we're doing," says Thomas Murphy, director of an EPA laboratory in Corvallis, Oregon. Notes David Rall, a former head of the National Institute of Environmental Health Sciences, "When there's a regulatory crisis at EPA, everything else stops."

A top-notch ORD chief could go a long way toward rectifying these problems, say environmental scientists: "If the agency is serious about improving its science," says University of Texas environmental engineer Raymond Loehr, who chairs the agency's Science Advisory Board (SAB), "it needs a

TWO REPORTS, TWO ADMINISTRATORS

In September 1990, a report from EPA's science advisory board (*"Reducing Risk"*) suggested ways the agency could improve its process of setting priorities and allocating resources. In March 1992 an expert panel offered suggestions for improving EPA science (*"Credible Science"*). Here are some of their major recommendations, and the responses of EPA administrators William Reilly, who served under President Bush, and Carol Browner, appointed by President Clinton.

Recommendation	Reilly	Browner
REDUCING RISK		
Tackle the most pressing environmental problems first	Tried to include more people in preparing budget	Asked SAB for advice, plans public meetings
Reduce ecological risks in protecting human health	Set up ecological monitoring and assessment program (EMAP)	Increased funds for EMAP, may be linked to biological survey
Emphasize pollution prevention over cleanup	Raised profile of emissions control	Continuing initiative
CREDIBLE SCIENCE		
Do more studies on potential long-term problems	Began small global change program (GCP)	Continuing GCP
Appoint a science advisor to oversee an internal council of scientists	Named William Raub, created council	Searching for Raub's successor
Incorporate science early in the regulatory process	Planned increase in research to support regulations	Formalizing role for research in planning regs
Recruit half a dozen "world-class" scientists	Interviewed candidates	Blocked by Clinton's plan to trim payroll
Increase share of funding for university researchers	Slight increase	Continuing small increase
Ensure quality of agency science documents	Developed internal peer-review policy	Continuing policy

strong scientist or engineer in charge of its science base." Researchers say it's also time for Browner and a new ORD chief to define the role of ORD. "Should we be gap fillers or national leaders?" asks Murphy.

Scientists also feel EPA's regulations often don't reflect the latest research. "There's been a lot of concern that policy decisions are made, then analyses are done to support the decisions," says Wendy Cleland-Hamnet, deputy director of EPA's regulatory management and evaluation office. Much of the blame for this lies with Congress: About 70% of EPA's budget is spent on carrying out congressional mandates in a dozen major environmental laws that direct EPA to minimize public exposure to specific toxicants and carcinogens. "The statutes simply make no room for science," says Reilly, now a visiting professor at Stanford. "Congress has already made up its mind as to how it wants things regulated."

One classic example is the Delaney clause of the Food, Drug, and Cosmetic Act of 1958. The clause prohibits EPA from allowing processed foods to contain residue from any pesticide known to cause cancer in animals and humans—no matter how remote the cancer threat. EPA would like to find a way around the legislation, and in March 1991, an internal EPA report recommended risk assessors ignore kidney tumors that develop after certain chemicals trigger a physiological cascade unique to male rats. But if EPA were to ignore such toxicological data in drawing up a regulation, says an EPA pesticides staffer, "we'd be in court in an eyeblink."

Congress isn't always the culprit, however; EPA creates plenty of its own problems in applying science to public policy. Last fall, for example, EPA funded a study suggesting that cleansing the soil of lead, which affects cognitive development in children, was unlikely to reduce lead levels in their blood significantly (*Science*, 15 October 1993, p. 323). But EPA ignored the finding and decided that cleaning up heavily contaminated soil would "measurably reduce blood lead." The lead industry criticized EPA's analysis, as did the Alliance to End Childhood Lead Poisoning, which thinks that it is more important to spend money on removing lead-based paint. EPA hopes to release a revised analysis later this month. EPA's attempt to set a standard for radon in drinking water is seen as another example of scientific ineptitude (*Science*, 17 September 1993, p. 1514).

Many scientists were hoping that two major reports commissioned by Reilly on strengthening EPA science would enable Browner to get off to a fast start. The first, "Reducing Risk: Setting Environmental Priorities and Strategies for Environmental Protection," urged the agency to do a better job of anticipating environmental problems. In response, Reilly asked EPA scientists to do two things: put greater emphasis on prevention, and spend more money on hazards that pose the greatest threat to humans and the environment.

Reilly didn't stop there. He asked for a second report on the agency's scientific efforts, "Safeguarding the Future: Credible Science, Credible Decisions," which reaffirmed what outsiders had said for years: "EPA science is of uneven quality, and the agency's policies and regulations are frequently perceived as lacking a strong scientific foundation."

One of the committee's key recommendations was to appoint a science adviser. "You need somebody to tell the emperor that he or she doesn't have any clothes," Loehr says. Reilly chose William Raub, who had spent 25 years at the National Institutes of Health (NIH), including 2 years as acting NIH director.

Raub assembled a council of advisers from the program offices and ORD and asked it to draft guidelines to, as the report requested, "insure a minimum level of quality assurance" for all science used to support decision making. He is also given credit for improving communications between ORD and the program offices. "The science adviser is an experiment that has worked," says Carl Mazza, chief scientist in the air and radiation office.

Reilly also pressured officials to focus on the nation's most important environmental issues. Suddenly, scientists working on dioxin in water began thinking about controlling dioxin release from incinerators and cleaning up dioxin at Superfund sites as well. "I really wanted to make science central to the agency's efforts," Reilly says. "But I think a fair amount of change is still necessary."

A time to act

Browner is taking several steps to elevate the role of science at EPA. She agrees with Reilly that the agency should emphasize preventing pollution rather than just cleaning it up, and she has begun to make more rigorous the review of risk assessments generated in the program offices. In addition, Browner plans to create a senior science policy council that will include scientists and administrators, and she wants more outside advice on the agency's efforts to set spending priorities. And next month EPA will conduct a series of national forums involving local and state officials, representatives of industry and environmental groups, and other concerned groups.

Browner also plans to add a research component to EPA's method of developing regu-

lations by asking agency scientists what additional studies need to be done before program offices can propose a new rule. Such an "analytic blueprint" would improve the quality of a proposed regulation, she says, as well as strengthen the agency's ties to its constituency of scientists, environmentalists, and industry representatives.

But Browner has yet to act on several "Credible Science" recommendations, including the hiring of four to six "world-class" scientists for EPA's in-house research program and shifting more research dollars to academic researchers (who now receive an estimated 10% to 20% of the agency's research budget). She has also failed to ease problems caused by a crackdown on abuses by contractors that has sharply eroded the ability of scientists to do research (*Science*, 29 October 1993, p. 647).

Browner says the Administration's efforts to reduce the federal payroll have hampered her ability to hire scientists. And "one of my greatest frustrations" since coming to the agency, Browner says, is how much time EPA scientists must spend managing contractors rather than doing research. Both problems may soon be alleviated, however: *Science* has learned the Administration will let EPA hire more full-time employees in 1995, allowing Browner to convert some contract researchers into EPA employees and to fill other positions with outside scientists.

With the environment a key issue for Vice President Al Gore, the White House is keeping a close eye on Browner's progress. And despite a spotty record to date in reforming EPA's science, most scientists are rooting for Browner to succeed. "When I first met Carol Browner, I was overjoyed," recalls Walker. "I got the impression she really, truly cared about science at EPA." He pauses for several seconds, then adds, "I still believe she cares."

–Richard Stone

MOLECULAR BIOLOGY

Italy Throws EMBL Into Turmoil

Fotis Kafatos, director-general of the European Molecular Biology Laboratory (EMBL), seemed to be well on the way to securing the lab's future just before Christmas. In a meeting at EMBL's Heidelberg headquarters, the lab's 15 member states backed "in principle" Kafatos' plan to spread research funds around by establishing a network of small EMBL-sponsored groups at centers across Europe (*Science*, 17 December 1993, p. 1807). This was expected to be enough to satisfy some countries' concerns that they hadn't been getting their money's worth from their EMBL contributions. But on 28 December, Kafatos' New Year celebrations were ruined when the Italian government dropped a time-bomb into his lap: formal written notice of Italy's intent to pull out of EMBL—an unprecedented move that throws the lab's future into jeopardy, because Italy provides 12% of EMBL's $50 million annual income.

To compound Kafatos' problems, Italian Prime Minister Carlo Azeglio Ciampi resigned last week, dissolving his transitional government and making any rapid change of heart impossible. "I really cannot say very much," a bitterly disappointed Kafatos told *Science* last week. "The reality is that I'm gathering my thoughts, the thoughts of the lab, and—very importantly—the thoughts of the [national] delegates."

Italy had threatened to quit last year because Italian scientists are underrepresented among the staff at EMBL's headquarters. By launching his "regional groups" program with four labs in Italy (and another in Spain), Kafatos hoped to head off the Italian threat. That hope is now dashed, but Italy has not yet closed the door on EMBL completely. The withdrawal cannot take effect until next January, which gives lab officials some breathing space, and the Italian notice came with a statement explaining that the decision "is intended to stimulate, within Italy and EMBL, a wide-ranging and deep analysis" of the reasons for Italian scientists' low involvement in EMBL. This debate may, the statement goes on, lead to "a relaunching of Italian collaboration in the European framework, including more positive developments vis-à-vis EMBL itself." These cryptic words, say Italian sources, mean that if the lab offers Italy more than the four regional groups promised so far, then it might not leave. The problem, however, is that this will require more money, which EMBL doesn't have.

Italian research minister Umberto Colombo could not be reached for comment last week. But Arturo Falaschi, director of the International Center for Genetic Engineering and Biotechnology in Trieste, says that the offer of just four regional groups was the final straw. Falaschi says a figure of ten was discussed at a meeting in Rome last October with Kafatos and Bernhard Hirt of the Swiss Institute for Experimental Cancer Research, then president of EMBL's governing council. Hirt, however, denies that any promises were made. "There was no secret deal," he says, adding that it was made clear that the ten-group estimate assumed a 5% growth in EMBL's budget, which its member states refused to consider in December.

With little hope that the other EMBL states will agree to increase their contributions to accommodate Italy, EMBL lab chiefs have been asked to draw up contingency plans for 1995, assuming no Italian funding. As most of EMBL's budget is locked into salaries and cannot be cut, new initiatives—such as the European Bioinformatics Institute now being set up in Cambridge, U.K. (*Science*, 18 June 1993, p. 1741) and the planned expansion of the EMBL facility in Grenoble, France—could be severely squeezed.

Fax campaign. Riccardo Cortese, trying to get the government to change its mind.

Many Italian biologists are dismayed by these events. "Isolation is always the beginning of death," says cell biologist Jacopo Meldolesi, director of the Department of Biological and Technological Research at Milan's San Raffaele Hospital, who argues that Italian molecular biology needs to increase its contacts with EMBL, not sever them. Riccardo Cortese, a former EMBL program leader who heads the Institute for Research in Molecular Biology in Pomezia, near Rome, is exasperated that his government—having won recognition that Italy's future involvement in EMBL must be increased—has allowed the debate to degenerate into penny-counting. "The issue now is a much smaller and less noble one," he says.

Meldolesi and Cortese are spearheading an effort to get the decision to withdraw reversed, bombarding the research ministry with faxes and telegrams of complaint. But with the government now awaiting elections in March, it is unclear what effect that campaign will have. The elections are expected to decimate the number of seats held by Italy's discredited Christian Democrat and Socialist parties, probably leaving the former communists of the Party of the Democratic Left as the largest bloc in parliament. The best hope for EMBL, it seems, is that this new government will be keen on pan-European initiatives. The problem with the debate over EMBL's future, laments Hirt, is that national considerations take center stage. "The word Europe is never mentioned."

–Peter Aldhous

Mr. CONDIT [presiding]. Mr. Wood.

STATEMENT OF RANDOLPH WOOD, DIRECTOR, ENVIRONMENTAL QUALITY, STATE OF NEBRASKA

Mr. WOOD. Thank you, Mr. Chairman. My comments are going to be a little bit different today. I am impressed with the academics that you have before you and I'm not going to address the subject of risk assessment from that perspective.

I'm representing the Governors, the Nation's Governors. The Governors are on the front line out there in terms of public health protection, in terms of protecting the environment. In terms of protection of the environment and protection of public health, the rubber meets the road in the States. The Governors have the responsibility. The Governors have, as I know you're well aware, lived up to that responsibility in the past, and they're committed to doing that in the future.

But they are frustrated. They have, as you're well aware with their positions on mandates, they have expressed a frustration that there is absolutely more to do than can possibly be done. They are frustrated with having to face small communities, some of which Mr. Thomas spoke this morning, the frustration of those small communities in being able to do the things that are most important to them locally because there is a mass of requirements that is coming to them.

And it's not a mass of requirements that come to them from the standpoint of which one do we do first? It's a mass of requirements that say we have to do all of those things. And when you have a small community, and I'm very familiar with the one that Mr. Thomas spoke of this morning, Chugwater, WY, you have a community of 300 to 500 people, and they don't have the resources to do the Clean Water Act, the Drinking Water Act, subtitle D of the solid waste regulations, and still have someone to keep the office open downtown, have police protection, fire protection, and those kinds of things.

The Governors, in their statement to you, are basically saying somewhere, somehow there needs to be a process which recognizes the priorities, recognizes that all risks are not equal, recognizes that we need to be able to establish some sort of comparison, and do the things that are most important first.

With that, Mr. Chairman, I will yield the rest of my time. Thank you.

[The prepared statement of Mr. Wood follows:]

T E S T I M O N Y

Statement of
Randolph Wood
Director of Environmental Quality
State of Nebraska

before the

Subcommittee on Environment, Energy and Natural Resources and the
Subcommittee on Legislation and National Security
United States House of Representatives

on

Risk Assessment

February 1, 1994

NATIONAL GOVERNORS' ASSOCIATION
Hall of the States • 444 North Capitol Street • Washington, DC 20001-1572 • (202) 624-5300

Good Morning, Mr. Chairman, my name is Randolph Wood. I am the Director of the Department of Environmental Quality for the state of Nebraska. I am here today to testify on behalf of the National Governors' Association, as well as for the Governor of Nebraska, E. Benjamin Nelson.

The protection of public health and state natural resources are among the most important responsibilities carried out by Governors. The expectations of an increasingly informed citizenry demand that states continue to exercise the lead responsibility for protecting the quality of the environment. State programs, not only have designed and implemented control strategies consistent with federal statutes, but they often go beyond federal minimum requirements in order to meet unique environmental needs within the state. As a result, states have become noted sources of innovation in the environmental protection field.

The issue of risk assessment and how it relates to environmental laws and regulations is of particular importance to Governors as they carry out the requirements of an increasing body of environmental law. Although the Governors are unquestionably committed to environmental protection, heavy demands on state resources make it imperative that taxpayer dollars are spent wisely. In fact, this morning, as part of the National Governors' Association (NGA) Winter Meeting here in Washington, D.C., the Governors are

expected to approve a policy statement expressing their continued concerns about unfunded federal environmental mandates and the need to base environmental protection priorities upon sound science and risk-reduction principles. I will be submitting this policy for the record.

Risk-based priority setting has been undertaken by a number of state environmental departments since the late 1980s. A 1991 NGA survey of state environmental planning activities found that twenty-one state environmental departments were involved in various forms of strategic planning that included a process for setting program and budget priorities, and that interest has been growing steadily. The effect of these state efforts, however, has been diminished somewhat by the inflexibility of federal grant programs and federal statutory and regulatory requirements.

State experience has shown that comparative risk analysis is an excellent tool for building support for environmental protection efforts because it provides an opportunity to view the environment as a whole and a means of measuring the success of these efforts. States have argued for many years that this perspective needs to be institutionalized at the federal level where bureaucratic "bean counting," internal agency incentives, and toxic-specific campaigns often have distorted the environmental agenda.

Comparative risk analysis projects have shown that scientifically based rankings often do not match the public's perception of risk. Many scientifically based rankings conclude that global climate change, ozone depletion, and indoor air pollution present some of the biggest risks, while polls often show that public concern is focused on issues related to Superfund sites, solid waste, and drinking water. Rising awareness of this political/environmental problem is one reason why comparative risk is worth undertaking.

The ranking of risk alone, however, does not identify how resources should be allocated. For example, several low-risk priorities may be addressed at a lower cost than one highly expensive strategy directed toward the top priority. A risk management strategy must involve a good assessment of the risks, but it must also evaluate the technical capacity to reduce the risks and assess the cost-effectiveness of risk reduction strategies. The long-term goal must always be to minimize overall risk.

The U.S. Environmental Protection Agency's involvement in comparative risk also dates back to the late 1980s. Under the guidance of the 1987 EPA Science Advisory Board report, *Unfinished Business: A Comparative Assessment of Environmental Problems*, EPA has undertaken several initiatives, including an agencywide plan and several ecosystem-specific projects. Program-specific changes have been hampered by the language of various environmental statutes that mandate specific actions and prohibit the consideration of costs. Because substantive changes on the program and regulatory level have not been apparent to states, the Governors urge Congress to require an institutional mechanism to incorporate cost-benefit analyses and risk-based decision making in a manner that is highly visible to both Congress and the public.

Cost considerations likewise need to receive more public attention in environmental rulemaking. A 1991 Environmental Financial Advisory Board report found that the cost-benefit analyses conducted by EPA have not received as much attention as they probably warrant and that the agency needs to build its capacity to conduct financial evaluations of regulations. It is important to make clear that the Governors' desire to bring cost-benefit issues to the forefront of decision making is in no way an effort to discourage environmental legislation and regulation or to say that less money should be spent on

environmental regulation. It is simply a matter of making sure we are spending money in the right places and in the right ways.

Although the Governors have been very supportive of the commitments expressed in Executive Order 12866 to assess all costs and benefits of available regulatory alternatives, its effect in the environmental area is limited by various statutory provisions prohibiting EPA's consideration of costs in rulemaking. Consequently, the Governors urge that the concepts be infused as broadly as possible throughout both the executive and legislative branches of the federal government.

I would note that in recent conversations with Administration officials, the Governors have been assured that the kind of analysis required by the executive order is being undertaken by EPA and other agencies. However, most environmental statutes specify in detail the process to be used in setting standards, such as prescribing the use of best technology, and, as mentioned above, the cost of compliance is precluded from consideration in some cases. This means that risk assessment and cost-benefit analysis, while it may be illuminating, may be of very limited use in guiding decisions on matters such as standards and technology requirements. For this reason, we believe that the use of risk assessment and cost-benefit analysis needs to be written into appropriate environmental statutes. I would note that the Governors' policy specifically recognizes that this analysis should encompass both quantitative and qualitative assessments.

One of the advantages of writing the risk assessment and cost-benefit analysis requirements into law is that doing so would establish a process as policy and would create a permanent mechanism. The use of analysis would also not depend upon executive discretion from one Administration to the next. Moreover, the law would provide for

reporting the results of the analyses to Congress and the public in an appropriate form, which we believe would improve public acceptance of EPA requirements and give the Congress important information for oversight. I would note that while the Governors support the use of these analyses, they are not advocating a hard requirement that EPA decisions depend upon the results of the analysis. There may well be instances in which EPA should and will publish a regulation after a cost-benefit analysis fails to demonstrate benefits in excess of costs. Even if that occurs, we are convinced that requiring the analysis will improve the overall quality of our environmental programs by increasing federal decision makers' awareness of the costs and benefits of their actions.

The Governors do believe that priority setting must result from the use of these decision making tools, however. The policy under consideration by the Governors that I mentioned at the outset proposes a means of priority setting for all new federal environmental laws and regulations. It suggests that if an environmental problem warrants the passage of federal legislation or the adoption of regulations, then states and local governments should receive federal assistance to carry out the resulting requirements. If funding is not provided, states and local governments should be permitted to carry out the related activities based upon their own priorities and programs. Finally, if new problems emerge that require federal attention, but additional federal resources are not available, the federal government should balance current requirements against any new requirements so that the highest priority work can be accomplished within existing budgets. As Senator Patrick Moynihan has said, "The choice is not between having priorities or not having them. Rather it is between setting them consciously or setting them by default."

The Governors' policy statement clearly reflects the day-to-day frustration of Governors and state officials like myself who often feel that state agendas have become the victims of

crisis-driven efforts and the sometimes ill-fitting federal solutions. The science of risk assessment may never be perfect, but the time has come to expand the consideration of risks, priorities, costs, and benefits in environmental decision making.

Mr. CONDIT. Thank you, Mr. Wood. Mr. Hirl.

STATEMENT OF J. ROGER HIRL, PRESIDENT, OCCIDENTAL CHEMICAL CORP., ON BEHALF OF THE CHEMICAL MANUFACTURERS ASSOCIATION

Mr. HIRL. Thank you, Mr. Chairman. I come here as president of Occidental Chemical Corp. but also representing the Chemical Manufacturers Association. The Chemical Manufacturers Association represents approximately 90 percent of the productive capacity of our industry, some 180 companies of all sizes.

Unfortunately and frequently, many people suspect that when industry—the chemical industry in particular—gets on a soap box and calls for a new approach to regulating threats to human health and the environment, we are secretly urging policymakers to go easy on us, to roll back environmental regulation.

Mr. Chairman, I want to be very clear about one thing. We fully support the objectives of our Nation's environmental policies. We simply question the methods used to achieve those objectives. We would like to see a system of regulation that, to quote from Vice President Gore's Reinventing Government initiative, "works better and costs less."

And we're not alone. President Clinton himself, Administrator Browner, Senators Moynihan, Baucus, and Johnston, Representatives Brown and Moorhead, and environmental leaders like Jonathan Lash, Gus Speth, and Russel Train all say that the old command and control system of regulations—a system that has, in fact, accomplished much, a great deal over the past two decades—has become unreliable and ineffective.

We think the time has come to better allocate our resources to improve human health and the environment and make objective risk considerations a key part of the policy debate. These considerations would make a good idea—elevating EPA—even better.

The solution to better public policy, we believe, lies on the path of continuous improvement, a never-ending pursuit of better products, better processes and less waste. It means doing quality work the first time, every time.

Commitment to continuous improvement has revolutionized business, Mr. Chairman. We think it can do the same thing for public policy. How? We suggest four criteria when formulating these policies.

First, set priorities guided by risk considerations. We should aim to allocate our Nation's resources in those areas when we can get the greatest risk reduction for the resources spent; to use the colloquialism, the biggest environmental bang for the buck.

And those risk reduction efforts should be achieved in the most cost-effective manner. That doesn't mean accepting lower standards of protection. It simply means encouraging creative and innovative approaches.

Again, we're not alone in this belief. Let me give you an example. CMA recently asked nearly 325 thought-leaders from Federal, State, and local government, environment groups and the Nation's media about how the Superfund program could be improved. By an overwhelming margin, some 76 percent, these people said that site

cleanups should be performed in the most cost-effective way, provided the cleanup fully protects the community. We agree.

Next, methods for evaluating risk should be objective and based on scientific findings. Risk assessments and comparative risk assessments are simply, as stated many times, tools that can help us better understand a particular threat.

The more objective the risk assessment, the greater our understanding, and that allows for a more informed policy response.

Finally, we think public participation is central to the whole process. When the public is well informed and fully engaged, the result is most often good policy. Frequently it is said the public does not understand. I think we are underestimating the public and those who bring elected officials to office in their ability to understand these situations.

Mr. Chairman, we can reinvent or reengineer our Nation's regulatory system to make it work better and cost less. We think the time has come to critically reexamine, not the objectives of public policy but the means for achieving those objectives. The risk amendment to the EPA bill is a very important step in that direction. Thank you very much.

[The prepared statement of Mr. Hirl follows:]

CHEMICAL
MANUFACTURERS
ASSOCIATION

WRITTEN STATEMENT

OF THE

CHEMICAL MANUFACTURERS ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON ENVIRONMENT, ENERGY AND NATURAL RESOURCES

AND THE

SUBCOMMITTEE ON LEGISLATION AND NATIONAL SECURITY

COMMITTEE ON GOVERNMENT OPERATIONS

FEBRUARY 1, 1994

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Executive Summary

The Chemical Manufacturers Association (CMA) appreciates the opportunity to have J. Roger Hirl, Chairman of CMA and President and CEO of Occidental Chemical Corporation, present this testimony on the risk assessment and risk management issues being considered by the Subcommittee on Environment, Energy and Natural Resources and the Subcommittee on Legislation and National Security of the House Committee on Government Operations. CMA is a nonprofit trade association whose member companies represent more than 90 percent of the productive capacity for basic industrial chemicals in the United States. In its testimony CMA raises four issues:

I. The Need for Risk-Based Priority Setting

There is a growing realization that we are spending more and more on environmental controls, but that we are not spending that money in the most cost-effective manner to address the most serious problems. As Chief Judge Stephen Breyer of the United States Court of Appeals for the First Circuit concluded in testimony before the Senate Energy and Natural Resources Committee, "our regulatory system badly prioritizes the health and environmental risks we face." To better allocate our limited resources we need to implement a risk-based alternative, with strong and meaningful public involvement, for steering environmental regulatory priorities. We would even go further and urge the government to compare risks in a way that transcends the jurisdiction of individual agencies, so that we can engage in a broader and better informed debate on how to allocate resources most effectively to address the full array of public health, safety, and environmental challenges confronting our society.

II. The Need to Improve Risk Assessment Techniques and the Accuracy and Relevance of the Resulting Risk Assessments.

While risk assessment techniques have improved in recent years, CMA believes that a good deal more can be done to enhance the accuracy and credibility of the outputs of the process, particularly if the role of risk assessment in regulatory decisionmaking is to be expanded. To make risk assessments more accurate, reliable, credible and relevant, a number of activities must be undertaken: 1) Risk assessment methodologies and inference guidelines must be reviewed and revised where appropriate. 2) Agencies will need to develop a more complete and current database of relevant scientific information that includes all relevant data and that readily incorporates new data. 3) The default assumptions and inferences used and the resulting risk characterizations should include an evaluation of the probability that the estimated risk value approximates the true value. 4) Finally, risk

characterizations should include the best, most plausible, scientifically-based estimate of risk.

III. The Need to Encourage Flexible, Cost-Effective Approaches to Risk Management.

Once the nature and magnitude of risk have been identified, risk managers must consider the full range of options for reducing or eliminating risks. In selecting among those options, the goal should be to achieve the greatest risk reduction benefits in the most cost-effective manner. The most effective means of achieving that goal are not through prescriptive, media-specific regulation, but through a flexible, performance-based, multi-media approach. One example of how risk management policies should not be structured is the various use reduction initiatives that have been advanced at the federal, state, and local levels. These initiatives do not take into account the benefits of the chemicals, the relative risks posed by substitutes, if any exist, and alternative, less-costly methods of attaining risk reduction. In short, Congress should encourage performance-oriented rules that achieve significant cross-media risk-reduction benefits as cost-effectively as possible.

IV. The Need to Improve Risk Communication and Public Understanding of Risk Assessments, Relative Risk Comparisons, and the Costs and Benefits of Risk Reduction Actions

One of the main reasons why our environmental protection expenditures have been less effective than they might have been in reducing overall risks is that regulatory priorities have too often reflected misguided perceptions of risk. Policymakers, risk managers, and the public need to be given better information and a better framework for evaluating and comparing health, safety, and environmental risks. Specifically, agencies should: 1) develop public risk communication and education programs; 2) transmit all information about risk assessments, including ranges of plausible estimates, uncertainties and all assumptions and inferences used; 3) communicate risk to the public in the context of other familiar risks; 4) inform the public about costs and consequences of alternative risk management strategies; and 5) periodically prepare relative risk analyses. This information would enable a more informed Congressional and public dialogue about how our risk reduction resources can best be allocated.

This testimony also addresses the six questions posed by the Committee to J. Roger Hirl in an Appendix.

Statement of the
Chemical Manufacturers Association
on the Assessment and Management of
Health, Safety, and Environmental Risk

Introduction

On behalf of the Chemical Manufacturers Association ("CMA"), J. Roger Hirl, President and CEO of Occidental Chemical Corporation and Chairman of CMA, is pleased to present this Statement on the risk assessment and risk management issues being considered by the Subcommittee on Environment, Energy, and Natural Resources and the Subcommittee on Legislation and National Security of the House Committee on Government Operations. In addition to this statement, we have provided answers to the six questions the Subcommittees requested that we address in an appendix to this testimony.

CMA is a nonprofit trade association whose member companies represent more than 90 percent of the productive capacity for basic industrial chemicals in the United States. The chemical industry now provides approximately 1.1 million jobs for American workers, an overall employment level that has remained relatively constant over the past decade, even though the U.S. chemical industry has changed dramatically to enhance productivity and remain competitive in domestic and world markets. Today, the chemical industry is the leading U.S. exporter. Chemical exports

in 1992 totaled $44 billion, roughly 10 percent of all U.S. merchandise exports in 1992, and produced a net trade surplus of $16.8 billion.

The chemical industry wants to remain a productive and competitive sector of the American economy that can continue to (i) produce a myriad of products that enhance our quality of life, (ii) provide good manufacturing jobs, and (iii) contribute to the expansion of U.S. merchandise exports. At the same time, our member companies are committed to managing chemicals responsibly from the standpoint of health, safety, and environmental protection. To that end member companies are implementing specific Codes of Management Practices under CMA's Responsible Care® initiative. As discussed below, we believe that well designed approaches to risk assessment, complemented by flexible, cost-effective risk management practices, have a crucial role to play in reconciling what are sometimes viewed as the competing demands of productive, job-creating growth and responsible environmental stewardship. Accordingly, CMA strongly advocates the adoption of risk-based and cost-effective health, safety, and environmental protection policies from the local to the international level.

In the balance of this Statement, we want to address four broad issues: (1) The need to use appropriate risk assessment techniques to evaluate and set priorities for addressing health, safety, and environmental risks; (2) The need to improve risk assessment methodologies and the accuracy and relevance of the resulting risk assessments; (3) The need to encourage flexible,

cost-effective approaches to managing risk and achieving the most substantial risk reduction benefits with available resources; and (4) The need to improve risk communication and public understanding of risk assessments, relative risk comparisons, and the costs and benefits of risk reduction actions.

I. The Need for Risk-Based Priority Setting

According to the General Accounting Office, as of 1990, American industry and government were spending about $115 billion per year to control pollution and achieve environmental goals.[1/] Those expenditures are expected to increase to more than $160 billion by the end of the decade.[2/] Some estimates are even higher.[3/] These are large sums by any measure; they must be spent wisely. As Senator Baucus recently testified, the fact is: "We do not have unlimited resources."[4/] Indeed, as John D. Graham, Director of the Harvard Center for Risk Analysis notes,

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1/ See GAO Report to Congress, "Meeting Public Expectations with Limited Resources," p. 8 (June 1991).

2/ See Id.; GAO Transition Series, "Environmental Protection Issues," (December 1992) (hereafter "GAO Transition Report") at 4.

3/ See Extension of Remarks of Honorable Carlos J. Moorhead on the Floor of the House of Representatives, August 6, 1993 (estimating the cost of environmental compliance to exceed $185 billion annually by the year 2000).

4/ Testimony of Senator Max Baucus to the Senate Energy and Natural Resources Committee, November 9, 1993 (hereafter "Baucus Testimony") at 2.

> "the reality of scarcity is more apparent today than ever before. . . . [T]he scarce human and material resources devoted to environmental protection are resources that we cannot use to combat crime, educate our children, reduce poverty, improve health care, strengthen our national defense, and meet the basic needs of citizens and their families."[5/]

Clearly, with so "many problems to solve and [so] many difficult choices to make," our environmental policy, as Senator Baucus and others correctly observe, "must move in a direction that will give us the greatest return on our investment."[6/] What this means, Senator Baucus properly concludes, is that "we have to set priorities. We have to solve our most significant environmental problems first."[7/] Unfortunately, we have not been very successful in allocating our health, safety, and environmental protection resources most effectively. Instead, as a careful student of the subject, Chief Judge Stephen Breyer of the United States Court of Appeals for the First Circuit, has concluded, "our regulatory

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5/ Testimony of John D. Graham, Ph.D. before the Senate Committee on Energy and Natural Resources, November 9, 1993, at 2.

6/ See Baucus Testimony at 2; GAO Report to Congress, "Meeting Public Expectations with Limited Resources," June 1991, at 8 (our environmental expenditures must be made in a way that "yield[s] maximum returns on [the] investment").

7/ Baucus Testimony at 2. See also Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making (June 1993) (hereafter "Carnegie Commission Report") at 118 ("The economic burden of regulation is so great, and the time and money available to address the many genuine environmental and health threats so limited, that hard resource allocation choices are imperative.").

system badly prioritizes the health and environmental risks we face."[8/]

Judge Breyer's view is widely shared. Many close observers of the process have stressed that during the last two decades, "environmental policy has too often evolved largely in reaction to popular panics, not in response to sound scientific analyses of which environmental hazards present the greatest risks."[9/] The result, as EPA's Science Advisory Board noted in a widely quoted study, is that regulatory attention often has been focused on less significant environmental risks while, overall, our environmental protection efforts "have been . . . less effective than they could have been."[10/] In particular, as a blue ribbon Carnegie Commission panel recently observed, by setting priorities on a "chemical of the month" basis, we wind up overregulating some hazards, underregulating others, and reducing agency credibility.[11/] This clearly is not a sensible way to proceed.

[8/] Testimony of Stephen Breyer before the Senate Committee on Energy and Natural Resources, November 9, 1993, at 2.

[9/] Keith Schneider, "New View Calls Environmental Policy Misguided," New York Times, March 21, 1993. See also BNA Daily Environment Report, May 25, 1993 at E-1 (excerpting the Center for Resource Economics' Annual Review of EPA, in which the agency is criticized for spending the bulk of its budget and staff resources on pollutants considered to be relatively low risk by federal scientists).

[10/] See Reducing Risk: Setting Priorities and Strategies for Environmental Protection (September 1990).

[11/] See Carnegie Commission Report at 73.

Instead, we must strive to implement a risk-based alternative for setting environmental regulatory priorities. As stated in the GAO Transition Series Report: "Establishing priorities among programs on the basis of the risk to public health and the environment is one of the keys to improved environmental management."[12/] Senator Baucus made the point succinctly and forcefully in his recent testimony: "We need to . . . weigh the relative risks of different environmental problems and target our efforts toward the areas where we can reduce risk the most."[13/] Furthermore, as the General Accounting Office emphasizes, in setting risk-based priorities, we must emphasize scientific judgment, rather than being "dominated by public perceptions of risk."[14/]

This is not to say that public perceptions of risk should be ignored in setting the regulatory agenda. To the contrary, if the public is excluded from risk assessment and priority-setting activities, the results of these exercises will lack the broad-based public acceptance that is essential for effective regulatory policy. Again to quote Senator Baucus: "We must also keep the public involved -- we can only address priority issues if there is

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12/ GAO Transition Report at 8.

13/ See Baucus Testimony at 3.

14/ See GAO Transition Report at 8.

a public consensus for doing so."[15/] To achieve that public consensus, as the Carnegie Commission points out, efforts must be made to incorporate societal values into relative risk analyses.[16/]

For these reasons, and because various sectors of the public have important contributions to make to risk assessment databases and methodologies, CMA supports public input to the risk assessment and priority-setting process. To facilitate informed public participation in the process, governmental and private sector entities, as discussed in Part IV below, should promote education about risk assessment and risk management issues and should strive to ensure that the risk information they communicate to the general public is accurate, understandable, meaningful, and placed in the proper context.

Developing a scientifically-grounded relative ranking of risks that the public can understand and support is very important. But it is not enough. The relative ranking of risks must be combined with an evaluation of the feasibility, cost effectiveness, and other impacts of actions that might be taken to address the different risks. In a word, we must "compare the magnitude of the various risks faced by Society and then go after those that present the best opportunity for achieving a reduction in risk in a cost-

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15/ Baucus Testimony at 4.

16/ See Carnegie Commission Report at 75.

effective way."[17/]

In recent years, there has been a widespread recognition of this point. Building on the pioneering work of EPA's Science Advisory Board, others have been quick to echo the theme that we must target our environmental management efforts on the basis of scientifically sound evaluations of the relative risks to public health and the environment presented by different substances and activities. As noted above, the General Accounting Office has also espoused this position for the last several years. Congress has begun to appreciate the point as well -- as evidenced in a variety of legislative proposals, such as the Environmental Risk Reduction Act of 1993 (S.110) introduced by Senator Moynihan, and Senator Johnston's risk analysis amendment to the EPA Cabinet elevation bill (S.171). The VA, HUD and Independent Agencies Subcommittee of the Senate Appropriations Committee also demonstrated an appreciation of this point when it urged EPA to "develop a risk-based strategic plan which targets those areas which have the greatest opportunities for major reductions in risk."[18/]

[17/] Testimony of Dr. Roger O. McClellan, President and CEO of the Chemical Industry Institute of Toxicology and member of EPA's Science Advisory Board, before the Subcommittee on Technology, Environment and Aviation of the House Committee on Science, Space and Technology, May 4, 1993. See also EPA Science Advisory Board, "Reducing Risk: Setting Priorities and Strategies for Environmental Protection," (September 1990) at 6 ("EPA should target its environmental protection efforts on the basis of opportunities for the greatest risk reduction.").

[18/] See S. Rep. No. 137, 103d Cong., 1st Sess., p. 101 (September 9, 1993).

The importance of risk-based priority-setting has been recognized by the Executive Branch as well. Executive Order 12866, issued by President Clinton on September 30, 1993, directs each Federal agency, in setting regulatory priorities, to "consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction."[19/] The Order goes on to require each agency to prepare a Regulatory Plan of significant actions it expects to take and, for each such action, to show "how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency."[20/]

Overwhelmed by requirements to comply with a host of unfunded and inflexible environmental mandates issuing from Congress and Federal agencies, states and localities also have come to appreciate the importance of establishing scientifically sound, risk-based priorities for addressing health, safety, and environmental concerns. Warning of an impending fiscal crisis, a bipartisan group of Mayors from 114 cities and towns across the country have urged Congress to reject the view that "we just can't

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19/ Executive Order 12866, Section 1(b)(4), 58 Fed. Reg. 51735 (October 4, 1993).

20/ See Executive Order 12866, Section 4(c)(1)(D), 58 Fed. Reg. 51735 (October 4, 1993).

spend too much on the environment."[21/] Instead, the Mayors stated, Congress must "assure that environmental protection investments are made where they accomplish the greatest good."[22/] To provide such assurance, a report accompanying the Mayors' letter observed, it is essential to promote policies under which "risks are examined objectively" in setting environmental priorities.[23/]

A similar concern was expressed in a Resolution on Risk Assessment adopted by the National League of Cities in December 1992. Complaining about the Federal government's failure to prioritize the nation's environmental objectives and goals, the Resolution calls upon Congress and the Administration to "authorize and fund significant efforts to assess real and scientifically verifiable risk prior to requiring any action" and to "develop guidelines based on the results of scientifically verifiable risk assessment which would authorize regional authorities, states and local governments to prioritize the implementation of national environmental mandates based on actual regional, state and/or local environmental problems."[24/] Representative Carlos Moorhead echoed

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[21/] See January 15, 1993 letter to members of Congress from Tom Fink, Mayor of Anchorage, Alaska, and co-signed by 113 other mayors.

[22/] See id.

[23/] See "Paying for Environmental Mandates: A Looming Crisis for Cities and Counties," (September 1992) at 10, 35.

[24/] Resolution #93-14: Risk Assessment, adopted at the National League of Cities Annual Business Meeting, December 1, 1992.

the mayors' concerns in his floor statement introducing the Risk Communication Act, H.R. 2910. Noting the immense costs of environmental mandate for the cities, he concluded: "These mandates drain money needed for education, crime prevention and local health programs and often restrict the opportunities for businesses to compete and grow. Municipalities ... are will to ensure that their activities are environmentally responsible but cannot afford to expend great sums on excessively hypothetical and exaggerated risks."[25/]

The National Governors Association ("NGA"), too, has expressed dismay over the proliferation of underfunded and inflexible environmental regulations that often "exceed the financial and technical capabilities of the governing agencies" and "preclude the intelligent application of resources to problems."[26/] In a major policy statement on the issue, the NGA urged EPA to:

> "set risk-based priorities for environmental protection. EPA should target its efforts to reducing the most serious remaining risks to the environment and public health. Risk

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[25/]Congressional Record (daily ed. Aug. 6, 1993)(Remarks of Rep. Carlos J. Moorhead).

[26/] See "Cumulative Impact of Environmental Regulations," Policy Statement adopted by the National Governors Association in February 1993.

> identification and resulting environmental regulation should be the product of scientific study."[27/]

Many states and localities have initiated comparative risk analysis projects of their own in an effort to identify and rank the various environmental, health, and safety risks confronting their citizens. The Northeast Center for Comparative Risk ("NCCR") at Vermont Law School and its Boulder, Colorado partner, the Western Center for Comparative Risk, were established by EPA to provide technical assistance to states, cities, tribal governments, and regional bodies that are interested in moving forward with these projects. As the NCCR's Bulletin indicates, there is a great deal of interest in comparative risk evaluations throughout the country.[28/]

CMA strongly supports these initiatives for the risk-based setting of regulatory priorities by governmental agencies. We agree with the Carnegie Commission blue ribbon panel that "relative risk analysis [is] . . . a promising tool for promoting scientifically sound decision making about priorities."[29/] We also concur in the panel's view that EPA and other agencies having health, safety, or environmental responsibilities (e.g., OSHA, FDA,

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[27/] Id.

[28/] See, NCCR, The Comparative Risk Bulletin, Vol. 3, No. 9 (September 1993).

[29/] See Carnegie Commission Report at 81.

and the Consumer Product Safety Commission) --

- should conduct and periodically update relative risk analyses in order to develop what the panel refers to as a "broad-based risk inventory"; and
- based on the results of those analyses, should "develop strategies to address risks of high priority."[30/]

Indeed, we would go a step further, by urging the Federal government to compare health, safety, and environmental risks in a way that transcends the jurisdiction of individual agencies, so that we can engage in a broader and better informed debate on how to allocate resources most effectively to address the full array of public health, safety, and environmental challenges confronting our society. While environmental degradation and occupational health concerns should certainly figure prominently in such a debate, other issues -- including violence, highway safety, AIDS, inadequate childhood immunization programs, etc. -- also should receive appropriate consideration. When the nature, magnitude, and ability to reduce these other risks are taken into account, we may well conclude that many of them are being shortchanged in terms of resource allocation when compared to the progammatic pollution control and cleanup issues that occupy EPA's attention. It is instructive to note, for example, that in 1992, fully 40 percent of fatal occupational injuries were due to transportation accidents,

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30/ See Carnegie Commission Report at 75.

and 20 percent were due to assault and violent acts.[31/]

In sum, relative risk analysis, as John D. Graham, Director of the Harvard Center for Risk Analysis observes, "is a crucial tool for environmental policy makers that fosters analytical thinking about how scarce resources and public attention should be allocated."[32/] While relative risk analysis may not "by itself resolve regulatory issues . . . it can provide a framework upon which policy may be better formulated."[33/] If they do not take advantage of this "crucial tool," our elected officials, in the words of the Carnegie Commission, "cannot be expected to forge a better vision of how to reduce the risks we face."[34/] For this reason, relative risk analysis should be used to set health, safety, and environmental priorities at all levels of government.

Before leaving this issue, we should point out that CMA member companies utilize a variety of risk assessment techniques to help set their own priorities, goals, and plans for responsible product stewardship and environmental protection. For example,

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[31/] See BNA Occupational Safety and Health Reporter, October 6, 1993 at 506 (presenting data on fatal occupational injuries compiled by the Bureau of Labor Statistics).

[32/] J. Graham & M. Sadowitz, "Risk Analysis and the EPA Cabinet-Elevation Bill," Risk in Perspective (September 1993).

[33/] See Carnegie Commission Report at 81.

[34/] See id.

under CMA's Responsible Care® Pollution Prevention Code, CMA member companies establish priorities, goals, and plans for waste and release reduction based in part on an assessment of relative risk, and in part on overall community and employee concerns. Similarly, CMA's Responsible Care® Product Stewardship Code requires member companies to characterize new and existing products with respect to their risk, taking into account information about potential hazards and reasonably foreseeable exposures. Based upon such an analysis, Occidental Chemical Company has proposed a system for ranking product risk which includes heavy consideration of exposure. Once physical and health hazards of chemicals have been characterized, an estimation of exposure is used to describe risk. This helps to put the magnitude of the risk in perspective by describing product use in the chain of commerce. Sales volume and customer applications weigh into this formula so that priorities can be set and specific actions can be taken.

Following the type of risk analysis required by the Product Stewardship Code including a risk assessment, the Dow Chemical Company also decided to forego development of a potential new product based on its intended use and possible disposal into publicly owned treatment works. Risk assessments and relative risk analyses thus have an important role to play in the private sector, as well as at the governmental level.

II. The Need To Improve Risk Assessment Techniques and the Accuracy and Relevance of the Resulting Risk Assessments

As part of our support for risk-based approaches to priority setting and environmental management, CMA urges that continued efforts be made to improve risk assessment techniques in order to ensure that the risk assessments relied on by risk managers in the public and private sectors are as accurate, objective, and relevant as possible. While risk assessment techniques have improved in recent years, a good deal more can be done to enhance the accuracy and credibility of the outputs of the process,[35/] particularly if the role of risk assessment in regulatory decisionmaking is to be expanded, as we believe it should be. EPA appears to recognize this point. Thus, Deputy Administrator Robert Sussman recently told the Executive Committee of EPA's Science Advisory Board that the agency needs state-of-the-art risk assessment, so that it will be less subject to challenge for having overstated or understated risk.[36/]

In order to make risk assessments more accurate, reliable, credible, and relevant, a number of activities must be undertaken. For one thing, risk assessment methodologies and inference guidelines must be reviewed and revised where appropriate. A good deal of work already is underway in this area -- partly as a result of the Clean Air Act Amendments of 1990, which created a Risk Assessment and Management Commission and

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35/ Cf. Carnegie Commission Report at 81.

36/ See BNA Daily Environment Report, October 28, 1993, at A-5.

directed the National Academy of Sciences to prepare a report on the risk assessment methodology used by EPA which was release on January 19th of this year, and partly as a result of agency reconsideration and updating of various risk assessment guidelines.

In addition to improving risk assessment methodologies and guidelines, Federal agencies, with the assistance of the private sector and academia, will have to develop a more complete and current database of relevant scientific information.[37/] In developing this database, agencies should not take the narrow view that only positive findings (findings that show an association between exposure and adverse effects) merit consideration for purposes of assessing risks. As the Carnegie Commission correctly points out:

> "Negative findings (that is, findings that show no association between observed variables) would be equal candidates for inclusion [in a risk data inventory] along with positive findings. Journals - and investigators - sometimes reject negative findings as uninteresting. As a result, reliable evidence that suggests that a substance does not cause a hazard often may be unpublished and otherwise unavailable."[38/]

Such "valuable but underutilized information"[39/] should be taken into account as part of the risk assessment process and, as

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[37/] See Carnegie Commission Report at 81.

[38/] Carnegie Commission Report at 85.

[39/] Id.

provided in H.R.2910, the Risk Communication Act of 1993, should be discussed in the agency's risk assessment presentation.

While creating a more reliable and complete database for risk assessment is important, the effort involved will be in vain, unless the updated data and new scientific understandings of mechanisms of toxicity are incorporated into the risk assessment process in a timely manner. This point might seem obvious. Yet, as Lynn Goldman, EPA Assistant Administrator for Prevention, Pesticides and Toxic Substances, recently observed: "Hurdles for incorporating more science [into risk assessment practices] have become absurd."[40/] This situation cannot be allowed to continue.

The science of health hazard and ecological impact evaluation is constantly changing; new data are constantly being developed; and risk assessment techniques and methodologies are constantly being refined and improved. Risk assessments must keep pace with and reflect newly developed data and new understandings in the relevant scientific disciplines. A system that does not allow this to occur "ossifies science and embarrasses the agency."[41/]

Accordingly, EPA and other Federal agencies should

[40/] See BNA Daily Environment Report, October 28, 1993 at A-5.

[41/] See id.

establish a mechanism by which new scientific knowledge can be incorporated in a timely manner into risk assessment guidelines and used in risk assessments (and related regulatory determinations) for individual chemicals. At the same time, agencies must assure that their procedures allow an adequate opportunity for public comment on (and, where appropriate, independent peer review of) new scientific data on which the agency intends to rely in making risk-related determinations. The establishment of EPA's "IRIS" database, which was put together largely as an internal agency exercise from which the public was effectively excluded, is an example of what we believe is the wrong way to develop risk-related health and environmental information.

While incorporating new scientific data into risk assessments is important, it is not the complete answer to the problems that have characterized many agency risk assessments in the past. In order to increase the accuracy, credibility, and relevance of risk assessments, the default assumptions, methodologies, and inference guidelines that are used to deal with uncertainty must reflect reality and the resulting risk characterizations should include an evaluation of the probability that the estimated risk value approximates true values. All too often, agencies have employed a series of worst-case default assumptions and upper-bound probability limits which, when linked together and compounded, produce wildly exaggerated and wholly unrealistic estimates of risk. Particularly when the agency has

not dealt forthrightly and openly with the uncertainties underlying its estimates, the resulting risk assessment can result in a serious misallocation of health, safety, and environmental protection resources.

When a value or parameter relevant to an estimate of risk is unknown, agencies should employ uncertainty analysis techniques to identify the distribution of possible risk values and should report the range of these values, along with their probability of occurrence, to the public. As the Carnegie Commission emphasizes: "Single-value risk estimates . . . do not provide an indication of the degree of uncertainty associated with the estimate . . . [and] do not convey the conservative nature of some risk estimates."[42/] By the same token, the assumptions, judgments, inferences, and models used by the agency should be clearly explained and justified in the risk assessment, and their impact on the estimated risk values should be fully characterized.[43/]

Finally, in setting priorities and making regulatory decisions, agencies should emphasize the best scientifically and empirically-based estimates of risk. While a range of plausible estimates reflecting scientific uncertainty and limitations in the data should be discussed in the risk assessment, the "best

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42/ Carnegie Commission Report at 87.

43/ Cf. H.R. 2910, the Risk Communication Act of 1991, section 4(b)(3).

estimate" of risk, i.e., the most plausible estimate given currently available information and scientific understanding, should be identified clearly for risk managers.[44/] This "best estimate" of risk also should be communicated clearly to the general public in order to avoid the confusion, misperception, and undue alarm that is created when agencies emphasize unrealistic worst-case estimates of risk.

III. The Need To Encourage Flexible, Cost-Effective Approaches to Risk Management.

CMA believes in practical, effective, risk-based approaches to environmental management -- approaches that reflect sound science, that consider social and economic impacts, and that achieve significant risk reduction benefits in a cost-effective manner. A sound environmental management strategy must begin by considering the nature and magnitude of the risks to public health and the environment that are presented by particular substances and activities. This type of evaluation can be performed as part of the relative risk analysis that we believe should be used to set regulatory priorities.

Once the nature and magnitude of an environmental risk has been identified as part of the risk assessment process, the full range of options for reducing or eliminating the risk should

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[44/] Cf. H.R. 2910, the Risk Communication Act of 1993, sections 5(1) & 7(3).

be considered. Ideally, these options would include:

- pollution and exposure prevention strategies -- broadly conceived to include source reduction, recycling/reuse, responsible management practices designed to minimize environmental releases, and enhanced control and treatment techniques;
- labeling and release reporting requirements for toxic chemicals; and
- in appropriate cases, programs designed to phase out particular applications or uses of a toxic chemical.

In selecting among these options, the goal should be to achieve significant risk reduction benefits in the most cost-effective manner, without causing disproportionate social and economic impacts. Unfortunately, with their emphasis on highly prescriptive media-specific regulation, the existing environmental protection laws frequently place obstacles in the way of such flexible, cost-effective regulation.

This point is well illustrated by the ambitious joint pollution prevention study recently conducted by EPA and the Amoco Corporation at Amoco's Yorktown, Virginia refinery. A key finding of the study was that if the company had been free to pursue a flexible, performance-oriented approach to pollution prevention, 90 percent of the emissions reductions required under applicable regulations could have been achieved for 20-25 percent of the cost of meeting the specific requirements of the regulations. In particular, had a performance-oriented approach to emissions

reduction been followed, releases at the refinery could have been reduced at an average cost of $510 per ton, as opposed to the $2,400 per ton average cost of achieving reductions under EPA's prescriptive command and control regulations.

Union Carbide Corporation is also experiencing frustration over the inflexibility and single-media orientation of most of our environmental laws. Because of requirements to meet inflexible effluent discharge limitations, Union Carbide may be forced to employ "end-of-pipe" technology at its Taft, Louisiana plant, rather than implement alternative source reduction projects (at a somewhat higher initial investment) that would achieve a greater overall reduction in waste generation and pollutant releases to all media, while enabling the company to recover valuable product.

These examples could be duplicated in a variety of different settings,[45/] but there is no need to prolong the discussion unduly. The point is simple: Soundly conceived environmental management policies, as President Clinton's Executive Order on Regulatory Review appears to recognize, must be flexible,

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[45/] Perhaps most familiar is the case in which a facility declines to process hazardous wastes that are amenable to treatment at the facility out of concern that the entire facility and all residues of the process would become subject to burdensome and costly regulation under Subtitle C of the Resource Conservation and Recovery Act.

cost-effective, and performance-oriented.[46/] Furthermore, they must reflect "a more integrated approach to solving our environmental problems,"[47/] and they must be designed to achieve substantial risk reduction benefits that justify the costs of the regulatory action. As the President recently stated in Executive Order 12866:

> "In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.
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> [T]o the extent permitted by law . . . [agencies should] propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs"[48/]

Having stated how sound risk management policies should be structured, we wish to pause for a moment to indicate how they should not be structured. Specifically, we are referring to the various chemical use reduction initiatives that have been advanced at the state, Federal, and even the international level. While they vary among themselves, all of these initiatives are animated by the implicit or explicit belief that the production and/or use

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[46/] See Executive Order 12866, Sections 1(b)(5), 1(b)(8), 58 Fed. Reg. 51735 (October 4, 1993).

[47/] See Baucus Testimony at 4.

[48/] Executive Order 12866, Sections 1(a), 1(b)(6), 58 Fed. Reg. 51735 (October 4, 1993).

of chemicals deemed "toxic" is inherently and unavoidably unsafe and should be banned or, at the very least, phased out as soon as possible. With this as their underlying philosophy, use reduction initiatives call for the creation of regulatory mechanisms that focus on eliminating the production and/or use of a designated list of chemicals, rather than on eliminating or controlling their release to the environment or their generation as hazardous waste.

In our view, these kinds of policies are short-sighted and counterproductive. In contrast to risk-based approaches, they proceed from the mistaken premise that the use of chemicals is necessarily undesirable and should be avoided. In fact, as John Graham and George Gray of the Harvard Center for Risk Analysis point out, it is not "clear that we should always promote less use of 'toxic' chemicals," since they often provide significant public benefits and can be used and managed in ways that "pose little or no threat to human health or the environment."[49/]

The more productive way to protect public health and the environment begins with objective, scientifically-based risk assessments. Then proceeds to consider the full range of risk management options and to identify and implement the alternative that will achieve the most substantial risk reduction benefits in a flexible, cost-effective manner, without imposing social or

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[49/] See J. Graham & G. Gray, "Optimal Use of 'Toxic Chemicals,'" Risk in Perspective, Vol. 1, Number 2 (May 1993).

economic costs that are disproportionate to the anticipated reduction in risk. The goal of such an approach is to reduce risk through actions designed to limit potential human and ecological exposures.

In pursuing this goal, there may be instances in which the imposition of mandatory restrictions on the production or use of a particular chemical will be appropriate. However, production and use restrictions should not be viewed as the presumptive risk management option of choice. Moreover, proposals for such action should be evaluated in a balanced framework under which all relevant factors (including the efficacy, costs and risks of substitutes, and the economic, social and competitive consequences of imposing the restriction) receive due consideration. The imposition of a use restriction would be appropriate only when a balanced evaluation of these factors leads to the conclusion that the risk associated with a specific use of a specific chemical would be unreasonable even after other risk management options were implemented. And such a conclusion should be reached only after members of the public have been fully apprised of the consequences of the use restriction and have had an opportunity to express their views on the risk management issues involved in the decision.

We believe that when risk management options are evaluated in a logical, step-wise manner under this type of balanced framework, prudent and feasible pollution and exposure

prevention programs will most often be selected as the preferred alternatives. This is the type of risk-based environmental management that Congress should encourage, by authorizing agencies to adopt flexible, performance-oriented rules that achieve significant cross-media risk-reduction benefits as cost-effectively as possible.

IV. The Need To Improve Risk Communication and Public Understanding of Risk Assessments, Relative Risk Comparisons, and the Costs and Benefits of Risk Reduction Actions.

Implementation of the risk-based approaches to environmental management discussed above will not be possible unless governmental entities and the private sector make a more concerted effort to improve the communication and public understanding of information relating to health, safety, and environmental risk. As noted above, one of the main reasons why our environmental protection expenditures have been less effective than they might have been in reducing overall risks is that regulatory priorities have too often reflected misguided perceptions of risk. In order for EPA and other Federal agencies to implement a more rational risk-based approach to regulation, the general public and members of Congress must be better informed about the nature of environmental risks and about the risk

assessment process itself.[50] After all, as M. Granger Morgan of Carnegie Mellon University points out: "In a democratic society, there is no acceptable way to make . . . [risk management] choices without involving the citizens who will be affected by them."[51] Accordingly, if we "want better, more reasoned social decisions about risk . . . [we] need to take steps to enhance public understanding."[52]

As part of the effort to achieve enhanced public understanding of risk, policymakers and affected sectors of the public should be given a better framework for evaluating and comparing health, safety, and environmental risks. They also should be provided with the information that will allow them to understand and evaluate the costs, benefits, and tradeoffs involved in implementing potential risk-reduction actions.

To accomplish these objectives, a number of steps must be taken.

First, agencies like EPA should develop public risk communication and education programs designed to promote an

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[50] See GAO Transition Report at 9 (observing that because "public opinion contributes heavily to the Congress's agenda, . . . the public must also be kept better informed about environmental risks").

[51] M.G. Morgan, "Risk Analysis and Management," Scientific American, July 1993, p. 32.

[52] See id. at 41.

informed and credible public dialogue on health, safety, and environmental risks and on the costs and benefits of options to reduce those risks. As part of these programs, agencies could prepare written and audio-visual materials that would be made available to the public -- both indirectly, through the media, and directly through state and local governments, educational institutions, labor unions, and other businesses and non-governmental organizations. Moreover, EPA should ensure that its publicly available databases, like the Toxics Release Inventory computer files and National Report, contain risk-related educational information.

Second, as noted in Part II of this Statement, agencies should be open and honest in communicating the results of their risk assessments. This implies a number of things:

- Agencies should not provide only single-value estimates of risk that reflect worst-case or upper-bound default assumptions, models, and inferences. Instead, a range of plausible estimates should be provided, along with their respective probabilities of occurrence, and the best scientifically and empirically-based estimate of risk should be identified.

- Agencies should identify and explain the significance of limitations and uncertainties in the data and in the scientific understanding of the relevant toxic mechanisms, dose-response relationships, exposure scenarios, etc.

- To the maximum extent possible, agencies should keep their policymaking-judgmental role separate from their function as scientifically objective

> risk assessors. To help accomplish this, any policy or value judgments and all significant default assumptions and inferences used by the agency in performing a risk assessment should be clearly explained and justified, and their impact on the estimated risk values should be properly characterized.

Third, agencies should communicate risk information in a manner that is understandable to affected employees or members of the general public and that provides a context for making relative risk evaluations. As part of this effort, agencies should compare the risks being addressed in the risk assessment to other risks that are familiar to, and regularly encountered by, members of the general public.[53/]

Fourth, agencies should inform the public of the reasonably estimated costs and other adverse consequences of alternative risk management options that might be employed to reduce the risks that have been identified in the assessment.

Fifth, as noted in Part I of this Statement, agencies should periodically prepare relative risk analyses, including rankings of the areas in which the most substantial risk reduction benefits can be achieved most readily and at lowest cost. The Executive Office of the President should combine these agency-specific evaluations into a government-wide relative risk analysis that could be used to identify risk reduction opportunities and

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[53/] See H.R.2910, the Risk Communication Act of 1993, section 5(3), and S. 171, Title I, Section 123.

priorities across the entire universe of health, safety, and environmental concerns. These analyses could serve as the basis for an informed congressional and public dialogue on how our risk reduction resources can be allocated most productively and effectively to the myriad of problems we confront in these areas.

While Federal agencies will have to take the lead in engaging Congress and the general public in a dialogue about environmental risk, the private sector has an important role to play in this area as well. CMA member companies recognize their responsibility to participate in risk communication and education activities with their employees, their customers, and residents of the communities in which their facilities are located. Toward that end, one of the fundamental goals of CMA's Responsible Care® initiative is achieving effective communication with the public, particularly in communities around chemical production facilities. Specifically, the Responsible Care® Codes require CMA members, consistent with reasonable protection of confidential business information, provide to employees, customers, and the general public information about potential risks associated with exposures to chemicals and chemical products that are (i) manufactured or used at their facilities, (ii) generated as waste at their facilities, or (iii) released from their facilities to the environment.

An example of our members' efforts to establish a

dialogue with plant community residents is seen in the over 215 Community Advisory Panels that have been formed throughout the country. These panels provide facility managers and the public with an ideal forum for sharing information and learning about their respective needs, CMA members have also been very actively involved in Local Emergency Planning Committees which further facilitate dialogue with the public.

At the same time, CMA recognizes that risk communication is a two-way street. Accordingly, we support efforts to gain greater insight into the basis of public concerns about chemicals and the chemical industry and to respond to those concerns. Toward that end, individual CMA member companies engage in outreach programs to educate local officials and citizens about their operations and emergency response procedures and to identify community concerns. Once identified, these concerns become the subject of a continuing dialogue with the community, and they are taken into account when CMA member companies set priorities and make decisions regarding the pollution prevention and other risk reduction actions that will be implemented at their facilities.

Conclusion

In closing, we want to reiterate our belief that scientifically grounded risk-based priority setting, combined with a flexible, performance-oriented approach to risk management, is the key to addressing health, safety, and environmental concerns in the most cost-effective and productive manner. Successful implementation of this approach requires continued efforts to improve and update risk assessment methodologies and databases, so that risk assessments will be more accurate and more relevant than the unrealistic worst-case estimates that too often have been relied on for regulatory purposes in the past.

At the same time, we must seek to ensure knowledgeable public participation in the risk assessment and risk management process. Toward that end, risk communication and education efforts must be improved, so that the public will better understand the meaning and limitations of particular risk assessments and will be able to compare relative risks and risk-reduction opportunities in a more informed and rational manner.

CMA intends to do its part to help ensure that the health, safety, and environmental objectives we all share are achieved as efficiently and effectively as possible, so that we can maximize overall risk reduction benefits while preserving the availability of products that enhance our quality of life, and the competitiveness and job-creating potential of our manufacturing industries. By encouraging risk-based priority setting and

flexible, cost-effective environmental management, Congress can make an enormous contribution to the achievement of this goal.

APPENDIX

Following are responses to the questions that Mr. Hirl was asked to address in his formal written testimony on behalf of the Chemical Manufacturers Association.

1. Should Congress mandate that Federal agencies, particularly EPA, reform their current risk assessment and risk management techniques and procedures, or are existing methods, including those contained in Executive Order 12866, adequate to insure reasoned decision-making?

Legislation is needed to ensure that resources--both private and public--are allocated most effectively to improve the environment, health, and safety.

The improvements needed to the current risk assessment and management processes to adequately "insure reasoned decision-making" are manyfold. A sound risk assessment reform would:

1) ensure that risk assessments are as accurate and scientifically-based as possible;
2) require that risk is characterized to both the public and the risk manager in a way that makes transparent any uncertainties, assumptions, and safety factors used in the risk assessment;
3) mandate that agencies use comparative risk analysis to help prioritize their actions and to consider the risks posed by alternative management strategies;
4) require agencies to seek the greatest risk reduction with the resources available by assessing the risks and benefits associated with alternative risk management strategies and selecting those that are the most cost-effective; and
5) require that agencies communicate clearly with the public, in terms they understand, objective information about risks and include the public in risk management decision-making.

This comprehensive approach provides a framework for making rational decisions about risk management and resource allocation. It offers a mechanism to take a holistic look at the risks posed to human health and the environment by all sources and to make informed decisions about how to reduce those risks to achieve the greatest net risk reduction. And it involves the public in the process. Currently environmental and public health problems are addressed in a piece-meal fashion. Legislative and regulatory schemes have been created to remedy unique problems arising in specific media or from specific sources. These actions are all too often based on perceived, and not real, threats and the goal of these programs has been to reduce or to eliminate the risks posed without regard to relative risk.

Executive orders and internal agency risk assessment guidelines cannot correct these deficiencies. They are not adequate to achieve real lasting improvement in regulatory decisions. No matter how well intentioned, these administrative measures are merely hortatory. They are not enforceable. And they can be easily withdrawn, modified or

ignored. For example, while EPA has issued risk assessment guidelines, as a matter of practice they are not uniformly followed. In addition, the programmatic, media driven regulatory structure of EPA is an obstacle to comparative risk analysis.

2) How important is comparative risk analysis to ensuring that Federal funds are spent on the most serious problems first? What are the pitfalls of using comparative risk analysis in setting priorities?

How can Congress and the President be sure that federal tax dollars are being spent in a way that provides the greatest benefit to the citizens of this country without assessing what are the greatest needs and setting priorities? Clearly, federal fund allocations cannot continue to be done by the "squeaky wheel" system or by the "chemical of the month" as characterized by the Carnegie Commission. Comparative risk analysis is an empirical way to identify and target the most serious risks. When comparative risk information is provided to the public it will allow for a more informed public discourse. Comparative risk analysis will not guarantee that federal funds are spent on the most serious problems, but it will ensure that allocation decisions are made with better information.

Comparative risk, as a tool to help make sound allocation decisions, is limited by the quality of the risk assessments that underlie it. Thus, one "pitfall" may be the potential for relying on inaccurate characterizations of risk, but this is true for the current system. Overly rigid application of comparative risk to set priorities could be another "pitfall." Comparative risk analysis alone cannot dictate how resources will be allocated. Risk managers should set their priorities with the goal of seeking to achieve the greatest overall risk reduction with the resources available. And other considerations (e.g., economic and political) will need to be factored into the decisions of regulators and policymakers. CMA believes that resources to improve the environment, health, and safety should be allocated in the most cost-effective manner.

3) Should agencies continue to use "conservative" assumptions in risk assessments, i.e, those containing sizable margins of safety, in order to take into account uncertain and variable factors when protecting the public health?

There is nothing inherently wrong with the use of assumptions when accurate information is unavailable, as long as the assumptions are scientifically plausible. Agencies rely on default assumptions by necessity. Nevertheless, the agency's use of assumptions should be governed by two principles:

1) The hurdle for replacing those assumptions with real data should not be so high as to discourage research to generate that data.
2) The assumptions used and the scientific and policy rationales for using them should be clearly identified in the risk assessment

as it is communicated to the risk manager and the public. The risk assessment should be transparent so that risk managers and the public can take into consideration the likelihood that risk assessments accurately reflect more plausible levels of risk when risk management decisions are made.

4) Should the focus of the Congressional debate be on improving the risk assessment process, on improving risk management or on improving public communication of the nature and degree of risk?

Risk assessment, risk management, and risk communication are inextricably linked and there is need for improvement in all three areas. Improving the risk assessment process improves risk management decisions. Scientifically sound risk assessment forms the basis for the comparative risk analysis. Finally, communicating more clearly and accurately about the absolute and relative magnitude of the risks to the public will generate better allocation of resources and wiser public decisionmaking because in the end such decisions are driven by public perceptions of risk.

5) How important is it to distinguish between risks produced by voluntary activities such as cigarette smoking with risks from involuntary activities such as breathing air or drinking water? Should these different activities be evaluated using the same standards and is it appropriate to compare environmental and non-environmental risks?

There should be no rigid rules for comparing risks. The appropriateness of risk comparison will depend on the intended use of the risk comparison.

Probably the most critical use of comparative risk is to provide the public -- those who actually incur the risks -- with information they can use to make informed choices. People need to know not only about the relative seriousness of risks addressed by the government, but also about the seriousness of the risk in terms of risks more readily understood and commonly encountered.

6) Will current efforts to statutorily prescribe the methodology for risk assessment lead to a "freezing" of science?

Any statute that prescribes risk assessment methodology or the degree of conservatism that should be employed in risk assessment may "freeze" science. The Risk Communication Act, H.R. 2910, does not specify how risk assessments should be conducted or what models or assumptions should be used. On the contrary, it encourages the development of new data by requiring that all high-quality data be considered. It requires the agency to identify and discuss alternative assumptions and models which can only have the effect of making the Agency more aware of current scientific developments. In short, that bill, if anything, would have the effect of opening up the process to ensure that improvements in science are incorporated into agency risk assessments.

Mr. CONDIT. Thank you, Mr. Hirl. I have a few questions that were inspired by reviewing the panel's testimony, and I will address them to the individuals, but if any of the panelists would like to respond to the questions, you're welcome to do so.

I'd like to begin with Dr. Finkel. You have recommended against the adoption of risk legislation because it undermines the needed improvement in risk assessments. Are you of the opinion that the President's executive has in any way undermined the needed improvements in this area?

Dr. FINKEL. I don't think it's been around long enough to tell. I am concerned with some of the language in that order. I think it's based on some of the same kinds of false premises that I talked about, but I recognize that there's a need to systematize, to encourage the work to be done, and I guess on balance, I'm supportive of the order, particularly because it emphasizes transparency and avoiding some of the procedural mistakes that characterized OIRA in past years.

So, on balance, I think it's a good thing but I get concerned with language like "objectivity" and "best estimates."

Mr. CONDIT. Anyone else like to respond to that?

Dr. WARGO. I just wanted to say that I think that the Executive order, the language within the Executive order is quite admirable. There's an interesting analog to the Executive order that was passed by Congress in 1970 in the National Environmental Policy Act.

That statute requires that any Federal agency that may have a significant adverse effect on the environment is required to prepare an environmental impact statement.

Now, that could be read to be the same quest for more formal, rational analysis that would precede government decisionmaking, as this committee is considering here today.

The regulatory process that has evolved following the passage of that law is quite complex, but they developed a very interesting scoping approach to problem definition, in that they scoped out that the largest problems are those that need the full-blown environmental assessment, whereas those that were less in scope would require only a lower-scale assessment. That kind of staging may be appropriate for your consideration of legislation.

Mr. CONDIT. Thank you very much.

Dr. Percival, your testimony, in the section titled "Regulatory Paralysis by Analysis," stated that at some point, the expense and delay of gathering and considering additional information is more costly than valuable. It seems to me that this is a valid problem, with or without risk legislation. In today's regulatory scheme, how is it determined when enough information has been gathered?

Are you saying the present system is adequate?

Dr. PERCIVAL. Congressman, I think that's a very difficult question. You have to be guided by common sense notions, in part, and also some understanding of what the value of the additional information is going to be. Is it that there is some data out there that we just haven't gathered that is likely to have a dramatic impact on how we design this regulation, or how extensive the coverage of the regulation is, so that there's a real potential that we could be improving the ultimate quality of the regulation?

Or do we know the substance is really toxic and we know a lot of people are exposed to it, but we don't have absolutely precise numbers? We could delay regulation for several years trying to get precise numbers, but it probably wouldn't do very much to change the ultimate regulation that's adopted.

So it's going to vary from case to case. Those are difficult judgments that hopefully are best left to the informed discretion of the regulatory agencies, and OIRA, in conjunction with the analysis that they perform.

Mr. CONDIT. Thank you, Dr. Percival. Dr. Graham, do you want to respond?

Dr. GRAHAM. Yes, I just want to make a point. I don't know anybody who's been advocating risk analysis legislation, that I've talked to, who's been advocating some kind of Cadillac version of risk analysis that has to be applied uniformly to every rulemaking.

I think Senator Johnston, in his testimony this morning, made it very clear that he's not talking about a Cadillac version of risk analysis all the time, and Sally Katzen made it very clear that in the existing Executive order, they tailor the amount of analysis to the importance and the stakes at hand.

When you're spending $150 billion a year on environmental regulation, to say that the cost of analysis is going to be excessive is really kind of an interesting kind of claim, and it would be interesting to see that documented in a few actual examples.

Mr. CONDIT. Thank you, Dr. Graham. You, Dr. Graham, advocate that Congress adopt risk legislation that covers all Federal agencies.

Dr. GRAHAM. Yes.

Mr. CONDIT. This morning I announced that I intend to introduce legislation that does just that. However, if legislation covering only EPA gains passage, would you envision problems in regulatory matters that are cross cutting, such as pesticides or wetlands lost?

Dr. GRAHAM. Well, first of all, the whole question of legislative tactics, of which is the best vehicle to get that, I have to be candid with you and say I'm certainly not an expert in the question of which vehicle is the appropriate vehicle.

But I had a sense, as I was listening to Sally Katzen, that, in a sense, if we could find a broader vehicle that would apply to a lot of agencies, you might, in fact, find more administration support for this. And from a tactical point of view, hey, if we can do that.

But on the other hand, when you have momentum building on an issue like this, it seems to me it's very important to take what you can as you go, and then keep moving.

So I would say we ought to do all we can in the different forms that we can to promote risk analysis.

Mr. CONDIT. Thank you, Dr. Graham. Anyone else want to comment on that? Dr. Wargo.

Dr. WARGO. You mentioned the issue of pesticides and I think that EPA has the primary responsibility for setting regulations for pesticides. So that in that case, I think that a bill that moved forward that addressed EPA would sufficiently cover the pesticide arena.

Mr. CONDIT. Thank you very much. Mr. Hirl.

Mr. HIRL. Yes, if I may, the issue of the question of whether just choosing EPA as the agency to cover under this bill, first of all, let us understand that the EPA has very broad regulatory powers over all of industry.

So that when we have an opportunity, which we need to have, to introduce that tool, which everyone agrees is a very good tool—it is not the total answer, but it is a tool—then I think it's time to use this opportunity to implement risk assessment and risk management into the process, through the legislative process.

Mr. CONDIT. Thank you very much. I will turn to Mr. Clinger for questions.

Mr. CLINGER. Thank you, Mr. Chairman, and I thank the panel for appearing before us today. Your viewpoints are very helpful to us.

Professor Graham, one of the charges that's brought against using risk assessment or risk analysis, is that this is an underhanded way of diluting or reducing environmental protection; in other words, that this is an effort to take away the commitment that we've had as a Nation to really cleaning up our environment.

But it seems to me that you could also say that what we're talking about is using resources which are clearly not unlimited in a more rational, sensible way. In other words, is it your view that risk assessment or risk analysis can be used in a way that would focus our resources more effectively?

Dr. GRAHAM. Yes. First of all, I think that's a good question. Many of my students, when they come to the Harvard School of Public Health, and they haven't yet taken courses in risk analysis, or cost-benefit analysis, they come with a sense that gee, isn't this some kind of tool that's going to be used to try to say you shouldn't do things that are in the public interest?

And it's interesting. When you watch students read EPA's cost-benefit analysis of the phaseout of lead in gasoline, they see a very strong case made in that particular example for more stringent regulation, I also require them to read some of the work I did myself on the costs and benefits of putting automobile air bags in the driver's side, in the front right passenger side of automobiles, and you calculate the expected number of lives saved, the injuries averted, and compare them to the cost of the airbags, I think the people who are most paranoid about risk analysis tend to be people who haven't done a lot of risk analysis and haven't shown, particularly in cost-benefit analysis, that the answer can come out on both sides of the equation.

One of the things I liked about Sally Katzen, in her opening remarks, she said we're not here for less regulation, we're not here for more regulation, we're here for smarter regulation, and that's precisely what risk analysis is all about.

Mr. CLINGER. Certainly I agree with that. If the risks are really great you're required to give equal consideration, versus having a universe as big as the world that you're supposed to be focussing on and then somebody gets shortchanged. Whereas, if you are able to be more analytical in the way you go about it, you can focus on those areas which clearly need greater attention and a greater allocation of resources to those areas.

So it seems to me it really has promise to improve, rather than degrade, the quality of environmental——

Dr. GRAHAM. But I think it's an important point to make because there are a lot of people who aren't sold on that, who fear that somehow, risk analysis and cost-benefit analysis, is sort of an evil attempt to mysteriously undue regulatory programs. And we have work to do to get the message out that that is not the intent of risk analysis and cost-benefit analysis.

Mr. CLINGER. One of the reasons to hold this hearing is basically to begin to make that case.

Given the present status of things I would ask Judge Breyer, what can EPA be doing better presently than they're doing now, in terms of risk analysis?

Mr. BREYER. Well, you'll have to ask people who are more familiar with the details of EPA. I've been very interested in listening to this hearing because in a sense, nobody disagrees and in a sense, everybody disagrees.

I mean, the administration, Senator Johnston, you, all think that what you should do when you're spending billions of dollars of public money is prioritize. I would imagine most environmentalists, too, would think it's much better to spend money to save more lives than spend it to save fewer lives.

And I would think, as you've heard that industry too would not object so much to the Nation's dollar commitment to safety and the environment, but industry would want the money to be spent sensibly.

So, you have a pretty broad consensus. I won't say 100 percent because not everybody thinks there's a prioritizing problem, but I think 90 percent do think so. But you also see a problem of trust.

Some worry that a statute which says "cost-benefit analysis" or "risk analysis," will be used to throw sand in the gears of progress. That is possible. And there are many people who worry about that.

At the same time, other people say, unless Congress creates a symbol by saying "Do something," it will be business as usual. And business as usual means a lot of money spent in ways that, from an environmental and safety point of view, are not effective. So that is Congress' problem.

If you pass this bill, it will be a symbol. If you don't pass it, you can take Sally Katzen at her word that the White House will do anyway what the bill seeks. And you can use oversight to make certain the money's being spent effectively.

My own solution, which is a beginning, is to say give the White House and OMB a chance to prove that they can use discretionary authority in a manner such that afterwards the environmentalists will say, "I'm glad we did that. I'm glad we gave the White House that power. It worked out in a way that saved more human life."

If I were trying to write a statute, I'd take $1 billion or $5 billion out of the Superfund and say, "We've removed the legal constraints Mr. President, except for one. You spend this money on one condition: that you come back three years from now and show us that you used it to save more human lives than would otherwise have been saved."

Do you see my point? My point is that it will help to give the White House more discretionary authority under the constraint

that it be used to prioritize better. As to what legislative words you use to accomplish that result—that is why you are here.

Mr. CLINGER. Thank you very much.

Mr. CONDIT. Thank you, Mr. Clinger. Mrs. Thurman.

Mrs. THURMAN. Professor Percival, you kind of looked a little red when Judge Breyer was over there talking, so let me ask you something.

Dr. PERCIVAL. Sure. Not that I disagreed with his statement at all.

Mrs. THURMAN. But let me follow up with what he said and let me see if you can respond to this. What tools would you use, if you were sitting in our seats, with a finite amount of dollars, understanding that there are risks, what tools would you use?

Dr. PERCIVAL. I would use the traditional tools, such as the kind of oversight hearing that you're doing right here, to analyze precisely what the Agency has done and what the results of the Agency's actions have been.

There was a lot of talk this morning about the problems that the regulated community faces because of getting a lot of conflicting statutory directives and not being given the resources to implement them. I think that's certainly one of the problems that EPA has had, as well.

Because the environmental statutes are written to require quite different types of standards and to promise quite different agendas it would be very surprising if the Agency's priorities were all perfectly in line with what God, as some ultimate risk assessor wanted the Agency to do.

But the true test of whether or not this committee and Congress are serious about improving the quality of regulation, which everyone in business and the environmental community and Congress should want will be whether if you do pass this legislation, you follow up by giving EPA the resources to implement it.

Part of our problem, part of the reason why we do have skewed priorities at times is because Congress not only imposes unfunded mandates on the regulated community, but also on the agencies that are supposed to implement the regulatory schemes. It would be most helpful to be willing to commit resources to the kinds of mandates that you're giving the agencies.

Mrs. THURMAN. However, you kind of take me full circle, then, because for me to make a decision based on what you just said, making real priorities, what tools do I have, as a Congressperson, to make that decision.

Let me give you an example in this committee. Not to downplay anybody's constituency, but I listened for 4½ hours about carpets. It was a very serious issue to those that were affected by it. I don't know what resources were spent by the EPA, but I know that there was some. And yet in the same time period, I hear about lead. I live in Florida and I could talk to you about sugar, or pesticides that are being used in areas of agriculture. I have some other issues that I'd like to talk about at another time.

But that's the question. At what point do we, as policymakers, make those hard decisions with a finite amount of dollars, what do we use to make those choices? You're not giving me anything.

Dr. PERCIVAL. You have to do precisely what you're doing now. Although this isn't a panel on which EPA is represented, grill them to justify what they're doing, why they're doing it, why it was important to do this, and how they use the limited resources they were given.

I suspect that one of their responses would be, "Well, you tied our hands." After they did the "Unfinished Business" study and the followup report "Reducing Risk," they said, "Well, we would like to change our priorities in a way that's more in line with the results of comparative risk assessment." And I think that's precisely the kind of thing where comparative risk assessment can be very useful, as opposed to requiring it for each individual regulatory decision.

But they said, "Our budgetary authority is so tightly bound to certain things that we have to do, that we maybe have control of over 5 percent of our budget." This is why Judge Breyer's idea of: "Hey, let's give them a pot of money and say, 'Go out there and show us that you can do, when freed of the kinds of constraints that we put into a lot of legislation, to get bigger bang for the buck'" is really an excellent idea.

Mrs. THURMAN. And I don't disagree. Mr. Chairman, can Dr. Finkel maybe answer?

Dr. FINKEL. I just wanted to get to your question about tools. I think, picking up on something John Graham said earlier, that it's easy to say that you're proanalysis. The devil is in the details. And I think some of the problem I see with the priority-setting concept is that again, the wrong questions are being asked.

The questions about whether carpets kill more people than lead does or however you want to phrase that—questions such as: "What's the worst risk? Where are the most lives being lost?" Those are intellectual questions. Questions such as, "What should we do next? Where could we, given the technology, the resource constraints, the human constraints, where could we make the most difference?" Those are the practical questions.

And I think you can answer the practical questions with, to borrow from Judge Breyer, tunnel vision about the risks abstracted from the costs of the intervention, the efficacy of the intervention, and the benefits to the public of the intervention. And we're focusing, in the legislation and in the Executive order, on the scientific side of the equation and ignoring the human factors and the cost factors.

We talk about the $150 billion or $200 billion—whatever the number is—on how much this costs, but all these regulations are transferring resources, creating losers from regulation as well as winners. And the losers are the ones who are organized to complain, and the winners are the ones who are quietly going about their business.

Mrs. THURMAN. Dr. Wargo.

Dr. WARGO. I think your question is a very important one. I think that throughout the different programs that EPA has, that they should make a very conscious effort to try to establish priorities. I know that they're doing that and I know that the Executive order that we've heard about today requires them to do that.

Within the pesticide arena that I'm most familiar with, it's my firm belief that we could reduce risk of carcinogenic outcomes by probably 95 percent by regulating more carefully less than 10 percent, probably less than 5 percent of the compounds on the market.

We should be developing strategic risk reduction plans to allow us to do that, not just for pesticides but for indoor air pollution, for hazardous outdoor air pollutants, for our safe drinking water standards. For each of these arenas, we should develop strategic risk management plans with priorities, and also allocate funds for the types of risk analyses that we all agree are necessary and the types of cost-benefit analyses that we also all agree are necessary.

There's a significant issue that this committee hasn't addressed yet that's relevant to the risk assessment and cost-benefit assessment. I'll go back to the title of my talk, and that is how do you control the bias?

One way of controlling bias that creeps not just into risk assessments—it creeps into cost-benefit assessments, as well, in very subtle ways: what types of costs do you consider? What methods do you use?

One way of controlling the bias is using the mechanism of full disclosure, requiring the agencies to make their data available to the public, make their methods of analysis available to the public, and to basically lay out the rationale for their choice among policy alternatives.

So, my response is full disclosure, and it's also strategic risk management planning, program area by program area.

Mrs. THURMAN. Are we going to get another round?

Mr. CONDIT. Yes, I could do that, if you like. I would like to, if I can, go to Mr. Mica, and then I'll come back to you. Mr. Mica.

Mr. MICA. Thank you, Mr. Chairman.

Dr. Finkel had said earlier that—I believe it was Dr. Finkel who said we have a fixation with a nonproblem. In other words, all of the cities and counties and the Governors and the businesses and industry and agriculture are all working under some kind of an illusion. Is that what you're saying, that there's a nonproblem here?

Dr. FINKEL. No, I'm not trying to trivialize the resources that go into this. What I'm saying is that the fixation on the belief that these resources are all skewed because risk assessment produces hype, that it produces an exaggerated sense of fear, I think that's a nonproblem.

I think there are better ways to spend that money. But to start with the premise that what needs to be fixed is some inherent scare tactic that comes out of risk assessment, I think that makes you lost from the beginning.

Mr. MICA. But there are definitely problems out there, real problems that need to be addressed.

Dr. FINKEL. And there are real health problems that need to be addressed.

Mr. MICA. Judge Breyer, you said give the President authority. Do you feel he has the authority to act and make sense of all of this and institute some risk assessment?

Mr. BREYER. Yes, but when I say "more discretionary authority," rather than "risk assessment" its because "risk assessment" is a

complicated thing. It's not an answer. People can misuse it. It can be used to tie things up for years. Dr. Finkel gave a few examples.

Insofar as risk assessment focuses on the question of the best way to use the money to save human life? Fine, let's do it. You've also heard that OIRA, using an Executive order, will take existing legal authority and using that existing authority, try to take proper prioritizing decisions and encourage people to use risk assessment.

The President has some discretionary authority already. He also has a set of statutes that bind EPA in 1,000 different ways. The difficulty with Congress trying to prioritize, I think, is that Congress is happiest making judgments between programs. But it's also true that you don't want to spend $1 billion improperly within a single program, spending it all, for example, to deal with instance X, where, in fact, if you spent $900 million you could also deal with three other instances.

So that kind of task, allocating within programs, or between programs within EPA, is difficult to accomplish through legislation. It is the kind of matter where I think giving discretion to the executive branch would, in fact, be helpful. But you'd have to see that the executive branch used the discretion to do what you want, which is to save more human life and deal with the environment more effectively.

Mr. MICA. But Your Honor, you didn't answer my question.

Mr. BREYER. That's the way I evade them sometimes.

Mr. MICA. My question and comment is I don't think that the President really has the authority, particularly through the vehicle that's been presented as an Executive order here.

And what I'd like to do is also ask Dr. Graham a question, if I may. Given the context that we're here today, we're here in a certain place and time. Congress has passed a nonending list of regulations, laws that promulgate regulations and give the agency the authority to do this. That's one of the problems. We've tied the place up in little knots. We've had testimony after testimony that says that EPA lacks focus.

What we're attempting to do is not correct all the problems of all the government agencies here, but in a rare meeting of the stars and the constellation and the Moon in the right place tomorrow, we're going to take up the EPA elevation bill, which is a rare occurrence, to create a Cabinet position.

Do you think that we can craft language, whether it's the Johnston amendment or some compromise, to give the legislative authority, to give the agency and the President, the flexibility and true authority that they need to develop some focus?

Dr. GRAHAM. Let me first confess that academics aren't very good at pragmatism. So I guess my response to you is that I'm sympathetic as you articulate the opportunity that's available on this particular bill that will be considered. So I do support taking the opportunity, pragmatically, when it's available to you, even though you can't do it in the most ideal and comprehensive form that Sally Katzen, for example, might prefer that it be done.

One quick addition to one of Adam Finkel's comments that I want to endorse. Some of the risk analysis bills that are in the Congress are only focussing on the risk assessment, the risk management and the risk communication questions, which are all very

important questions. But something that's very distinctive about both the Executive order and Senator Johnston's amendment is they explicitly relate risk to the cost of achieving risk reduction.

And I think it's very important, in whatever the final versions are that come out of this, that we have not only a discussion of risk, but we have a discussion of the cost of reducing risks, the relative costs, because I think otherwise, as Adam said, we're sort of focussing on one side of the picture and not on the full piece.

Mr. MICA. But my question again goes, if we give the authority in a legislative directive, then we can let the agency work out the details. And you can argue about all of these details and the proper manner in conducting risk assessment. Is that something you would encourage us to do?

Because right now, we're dealing under the laws, the plethora of laws that we've created here, the agency is going off, and they do have a charter on all of these demands, but we have limited resources. We don't have the ability to conduct every one of these mandates that we impose at the Federal level or pass on to State and local governments or to industry and business.

So again, my question is absent that authority, do you think we can approach it in the fashion—and we're only talking about EPA, one agency, at this point, which could, in fact, approve a model for risk assessment approaches in other agencies.

Dr. GRAHAM. I certainly think you need to do broad-based risk analysis, cost-benefit analysis authority across EPA, and some time in the future, across the Federal Government.

But one thing I want to add is that I hope you don't think that by doing that, that when we get to Superfund or the Delaney clause or the Clean Air Act, you can walk away from what you just did and then come back and create even worse problems than we have now in these laws.

So I want to emphasize that as much as you work on the generic part of the problem, and I think you should, for both symbolic and practical reasons, I still think that we have to observe your behavior and make sure when you come back on Superfund, you come back on Delaney clause, you're still in favor of risk analysis, you're still in favor of cost-benefit analysis, because you have a tendency to sort of slip on us on occasion.

Mr. MICA. We have a strong history of slippage. Thank you, Mr. Chairman.

Mr. CONDIT. Thank you, Mr. Mica. I would like to ask unanimous consent that members be permitted to submit questions to the witnesses and that the answers be made a part of the record. Any objection to that?

[No response.]

Mr. CONDIT. Mrs. Thurman, did you have a followup question?

Mrs. THURMAN. I'd like to go to Mr. Hirl, since he's working in industry right now.

Mr. Hirl, can you give us some examples of regulations that have cost more than you believe there was a benefit? Maybe you personally, or what you've been able to see, or what's come out scientifically since.

Mr. HIRL. Let me, first of all, if I can, just take an aside here because I have listened to the other members of the panel who are

from the scientific community and the academic community, and as a company and as an industry that's based on science, I quickly want to say that anything that uses good science is something that we want to support and have always supported.

However, much of this conversation is being conducted in the atmosphere, it seems to me, of infinite resources, and that's obviously somewhat a part of your question. We have finite resources, and I think it's imperative that we begin to legislate and require that people who impose regulations and legislation on industry, whether it's chemicals or otherwise, recognize the cost of that. So a cost-benefit analysis is essential.

One of the things that is very important to this industry, as we think it'll move forward in this year's Superfund, and the whole structure of Superfund and the requirements and regulations under Superfund and cleanup and so forth cry for risk assessment and comparative cost-benefit analysis. That is one that pervades not only us, the chemical industry, but all of industry. And that is an area where I think immense progress can be made by using scientific risk assessment, cost-benefit analysis, and recognize that a national standard at a high level will, in fact, not help the implementation of Superfund but rather, a scientific-based risk assessment.

Mrs. THURMAN. Let me ask something. We have found—in the Florida Legislature I worked on some administrative procedure issues—specifically that dealt with these types of problems, so that industry and citizens would have the opportunity to participate in offering alternative suggestions, so that if you had a situation where somebody came in and said, "Well, you need to do this, this, this, and this," and you said, "Wait a minute. Here is an alternative that's going to cost me less but will give me the same results."

Have you had any experience where we've seen a more friendly government that, in fact, will allow us to participate in that kind of conversation with industry?

Mr. HIRL. Let me answer that in two ways, if I may, and answer it from the standpoint of Congress and from the standpoint of the regulatory agency.

Historically, our industry has had an excellent communicative and, if you will, reg neg relationship with the Environmental Protection Agency. We have been able to participate. In fact, they have encouraged and asked us to bring forward data and information relating to what can be done; is there a better way to do it?

I think we have shown a commitment to that kind of compliance. We happen to have an industry initiative called responsible care. It is a program that requires our industry to not only deal with all of the issues of environmental regulation but process safety, and so forth. We do that because we know if we want to exist in the 21st century, we're going to have to do that.

The issue, as it relates to Congress, is simply a case of yes, we have been able to negotiate. We have been able, in our opinion, to impact on legislation that does affect us.

The question now is whether we are going to be able to do that in the future. Things have changed. The attitude of those involved in the regulatory agencies, in particular. The concern we have over

the issuance of Executive orders, which have broad impact on industry without the ability to discuss and the ability to impact those decisions.

We feel that there is a change. We want to introduce or see this scientific risk issue introduced as a requirement, to avoid a continuation of what I will call reduced impact, even though we have a lot of communication. The communication still exists. The impact seems to be questionable.

Mrs. THURMAN. Just to follow up, one of the things, and this may be way off base, but it seems that if you were looking at risk assessment or cost benefit, that when you look at a cost benefit, you also would have that opportunity to look at other things that are going through other parts of government, where it may not be just EPA but it may be something dealing with agriculture or something of that nature.

So that in fact, if you were doing some of these things, and any of you can respond to this that this is also an opportunity to go across the board looking at duplicative issues.

I'll give you an example. An accountant came to me a couple of months ago. He is also a county commissioner. He said to me, "You know what, Karen? I've just found out that it will cost the county $5,000, to do a federal highway program audit or something that they have to do. I have to do the same audit at the state level, with a few word changes, and it's going to cost me $5,000 more."

And this may not be a good example, but I'm sure when you're taking a Federal program to a State program that is when you're looking at cost benefit or regulatory relief. You also are crossing other agency/department lines that would help eliminate some of the duplicative problems that we're all very concerned about. This is a big part of the $430 billion deficit that our own Vice President said is costing business to comply with government regulations.

Getting back to the matter of finite resources, for every $1 that's spent, it's gone. It's $1 that can't be spent someplace else for other reasons. That's just a fact.

So if you can help me—but it seems to me, when you look at risk assessment and cost/benefit analysis, that there's a lot more advantage to it than disadvantage.

Mr. HIRL. Let me respond, and then I'll get off the table here and let someone else come on. The multiplicity, the breadth and depth of regulations that, in essence, are focussed on the same result, at various and sundry levels of government, is anathema for us as an industry. I think it is for industry in general.

And if I can, at least a little bit, take the message from the National Governors Conference, which Mr. Wood is bringing here, it's a case of understanding what you're doing within the total framework of regulation and legislation, not just look at it as a singular issue. That's the way we see it.

Mr. BREYER. I agree with what you say. I think it's quite important. That's why, in response to Congressman Mica's question, I said if you're really trying to do something about this, it's a bigger problem than just risk assessment.

If it were up to me, I'd like to see in OMB, OIRA, a group of people, who have experience in line agencies, experience in science and

public policy and government, as well as experience in law and policy analysis.

Then I'd say "I want you to do five things. The first thing I want you to do is prepare a book which will have the title 'Risk Analysis' or 'Risk Management' or both. It's not going to be a set of rules. It's not going to be 1,000 pages, and it's not going to be 3. It's going to be more in the range of 100 pages.

"To get the information that's necessary to write that manual you have to learn from the experience of many different agencies, not just EPA. People handle these matters differently in different agencies. You'll discover under each subheading and paragraph, the need for common sense judgment."

The paragraphs will be written at the level of generality in a manual about cost-of-service rating-making used for electricity, or trucking regulation. That kind of regulation was a hot political issue in the 1920's. People felt the same way about Consolidated Edison getting a rate hike much as they now feel strongly about toxic waste dump. But gradually rate setting systems developed, cutting across many agencies.

I'd ask OIRA to phone the people at this table, to obtain academic input. Academics are good at organizing material and developing systems but they sometimes lack factual information. OIRA also should go back to the people in the line agencies who know the facts.

My point is that you should put academics together with line agency staff. As a result, you might be able to write a short manual that offered the kind of cross-agency guidance that would be useful.

I would also say, "See if there aren't a very few uniform across-government rules in this area." One would be a kind of de minimis rule. It would have three parts. There would be something in the manual about four sentences long which would say not to take action that would cost more lives than it saves.

A third thing is to try to use the most up-to-date methods. That means talking to people who know about using sensitivity analysis, comparative risks in different areas and focus groups. There is a risk assessment "art." OIRA should stay on top of it.

A fourth thing is to take a small amount of money and try to transfer it within or even outside of EPA—say into HHS, where mammogram programs that could save a lot of lives of women over 50.

The fifth thing is to stay aware of developments in science. Once people begin to focus on particular genetic groups that are seriously at risk of cancer, we'll have a new dimension to the problem of trying to save people from risks of cancer.

In other words, I think what you say is important and, in fact, the key to this issue. The problem is beyond EPA. It's solution can begin at OIRA and OMB. I would encourage people there to begin.

Dr. PERCIVAL. Environmental regulation is clearly too complex and its complexity doesn't benefit anyone. It doesn't benefit the regulated community. It doesn't benefit environmentalists. It might benefit a handful of Washington lawyers. It certainly doesn't benefit State and local governments.

We need to focus more on how we can make environmental regulation simpler and more flexible and more sensible. And I'm

pleased with a couple of initiatives that EPA has been undertaking in this area. One is the notion that we might get a lot more bang for our buck if we also try to negotiate with industry the notion of voluntary reductions in the amount of toxic discharges. Let industry figure out the best and cheapest way to get those additional reductions, as an alternative to imposing a lot of new requirements for reductions that are going to be very complicated and expensive to achieve.

Mr. CONDIT. Thank you very much. Mrs. Thurman, does that conclude your followup questions?

Mrs. THURMAN. I have one or two more.

Mr. CONDIT. I hate to just move it along, but I need to do that.

Dr. WARGO. A very quick response. I think you put your finger on a very important problem, this overlap between Federal and State regulation. And all I can say is that if EPA did take a lead, perhaps in concert with other groups, such as the National Academy of Sciences, in trying to identify which are the things we ought to be worrying about and where we've made significant advances in our technical analyses, these advances spill down to the States.

I know for a fact that in the area of hazardous air pollution that Adam has worked on, or other public safety issues that John Graham has worked on, or the pesticide arena that I've worked on, when the Academy comes out with a report saying, "We think the risks are allocated in this area, and here are some reasonable management strategies," these help States tremendously.

So the effort that you would be supporting by either encouraging the Executive order or codifying it in law, I think, would have a direct influence in relieving the analytical burden from the States.

Mr. CONDIT. I would like to turn to Mr. Clinger. He has a couple of followup questions.

I'm sorry, Mrs. Thurman, did you—I'm going to have to do a risk assessment here in a minute.

Mrs. THURMAN. I was just going to say to Dr. Graham, I haven't ignored you, because I've been reading you for a long time, since I found out where you came from. And if you have a student that would like to have an internship, unpaid, in my office, I'd love to have somebody come work with me.

Dr. GRAHAM. They're going to be lined up outside the door. You can be assured of that.

Mrs. THURMAN. I said unpaid. Remember that.

Mr. CONDIT. With that, we'll go to Mr. Clinger.

Mr. CLINGER. Thanks very much, Mr. Chairman. I would just put in a plug for an amendment that I'm going to be offering tomorrow on the EPA bill which directs the Administrator to consider strategies for flexibility, for simplification, for looking at this universe and saying it's not a one-solution-solves-all, but let's work on a strategy to begin to address the complexity of what we're talking about.

I think there's some resistance to that amendment on the grounds, again, that it's perceived that it's going to be undercutting efforts to improve the environment. That's clearly the exact opposite of what I'm trying to get at here, that we really need to be promoting flexibility in the way we go about this.

Mr. Wood, the big buzz word these days is unfunded mandates. Gary and I are in a caucus that deals with unfunded mandates, and it's a serious problem, I think, in the Nation because as we run out of money, we have not run out of the things we'd like to tell the States and local governments to do. We continue to do that, but we are finding it hard to come up with the resources to give you to do it with.

How big a problem is that in terms of what you get from the Federal Government with regards to EPA? How large a part of the unfunded mandate problem is the EPA with the States?

Mr. WOOD. The discussion that I've heard today here focuses primarily on what kind of resources does the EPA have to do this job? And I'm real pleased you asked the question because, as I said earlier, the rubber meets the road in the State; the rubber meets the road in the local jurisdictions.

To give you an example, you talk about making it simple. How simple can you get it? We have communities in the State of Nebraska that are small communities, 65 percent under 500 population. As those communities look at complying with the Safe Drinking Water Act, as they look at complying with the Clean Water Act, in terms of waste water discharges, the list of regulations that Mr. Mica held up earlier is drowning those people, and here's what's happening.

They're looking at not tying into a public drinking water system. What they're looking at is disbanding the public drinking water system and using private wells. The regulations are driving them in the wrong direction.

These gentlemen, the academics, would tell you that in terms of risk to the public, that's the wrong thing to do. And at the same time, in terms of putting money into bringing their waste water treatment plants up to current and future specifications, they're looking at going to septic systems, disbanding the waste water treatment system. And then you've got drinking water wells septic systems sitting side by side, and I can let you imagine the risk that that has.

At the State level and at the local level, you can get just about any number you want developed by the various and sundry State associations of the million and billion dollar gap between what we have to do and the resources we're getting. And the National Governors' Association is adopting today, in fact, a resolution that says that if you're going to give us new mandates, you need to give us the money to do those things.

If you're not going to give us the money to do it, for heaven's sakes, give us the ability and the flexibility to determine, of those things on our plate, what the most important things are to do. Allow us to manage the risk. Allow us to put the resources where they do the absolute most good.

In the State of Nebraska, I've got a State revolving fund program under the Clean Water Act, and in addition, I've got a small community grant program. As a State, we try to put those together to enable those small communities to afford water system improvements.

But when I've got those small communities that have higher than the statewide median age, aging communities, and lower than

median incomes, and then look at the cost simply of paying the monthly bill for a waste water treatment, it gets to the point where it's a significant percentage of their income and they can't afford it.

That's the problem, and I know the Federal Government doesn't have a pot of gold at the end of the rainbow that you're willing to give us. So what we're saying, what the Governors are saying is, "Give us the flexibility to put our resources at the place where it makes the most sense."

Mr. CLINGER. Under the present system that EPA operates under, in terms of risk assessment, would it be fairer to say that the protocol basically escalates the threat and also increases the cost? Is it because there's a great deal of rigidity and inflexibility in the present procedure?

Mr. WOOD. That's the problem that we see. The Executive order, the discussions that we've heard have talked in terms of doing a risk assessment, and we all know that, as has been discussed today, that the individual laws themselves have stops on what can and what can't be done.

You can't, in the Safe Drinking Water Act, you can't look at the cost of compliance. You've got to go all the way to the best treatment technology. Those are the kinds of things that need to be looked at in concert with an overarching responsibility of balancing risks—doing a risk assessment. And an assessment is just a starting place.

The people on the ground in the States and local communities are going to have to then balance those. If we don't have the ability to do that statutorily, then I'm here to say, based on my 20 some odd years of running environmental programs in the States, that EPA is not going to be able to allow us to do that.

Mr. CONDIT. Thank you, Mr. Clinger. We're going to finish this, but you've made me think of something that we were talking about just a minute ago.

Mr. Clinger and myself, Mrs. Thurman, all of us have been extremely involved in unfunded mandates and how States and localities deal with that. Mr. Wood, you represent the National Governors Association. Have the Governors dealt with risk assessment on the State level? Do they have risk assessment programs? Does Nebraska have risk assessment?

Mr. WOOD. I'm glad you asked the question. There are some 21 States that responded in a 1991 survey done by the National Governors' Association and that's 3 years ago—that they, at that point, were doing comparative risk analysis, doing risk assessments, and trying to decide, of the limited resources, what's the most important thing to do.

And yes, we're doing that in our State. I have my agency budget. Governor Nelson said 2 years ago, "When you give me your budget, I want it to be a risk-driven budget. I want it to be based on priorities. What is it that you're not going to do? What's at the bottom of the list? What's at the top of the list?"

To do that, we've gone through the process of deciding what's most important in terms of protection of the public health and the environment. That's our yardstick. And so yes, we're doing that.

Mr. CONDIT. I want to thank all of you very much. You've done an outstanding service for the committee and to the citizens of the country, and I appreciate your being here very much. Thank you very much for your time.

Mrs. THURMAN. Mr. Chairman, could I ask Mr. Wood to give us those 21 other States?

Mr. CONDIT. Can you provide that list?

Mr. WOOD. Mr. Chairman, I will do that.

[The information can be found in the appendix.]

Mr. CONDIT. Thank you.

Mrs. THURMAN. Thank you, Mr. Chairman.

Mr. CONDIT. We'll take panel three, and we want to thank Dr. Lynn Goldman for her patience. She's been here all morning and we appreciate her being here and waiting all this time.

Dr. Goldman is the Assistant Administrator for Prevention, Pesticides, and Toxic Substances and vice chairman of the Science Policy Council for the U.S. Environmental Protection Agency, and we're delighted that you're here and we appreciate it. Dr. Goldman.

STATEMENT OF LYNN GOLDMAN, ASSISTANT ADMINISTRATOR FOR PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES AND VICE CHAIRMAN, SCIENCE POLICY COUNSEL, U.S. ENVIRONMENTAL PROTECTION AGENCY, WASHINGTON, DC

Dr. GOLDMAN. Thank you very much, and it's indeed been a very interesting morning. Let me array my things here.

Good afternoon. I guess we have Mr. Condit, Mr. Clinger, Ms. Brown and that's it for the committee. I'd like to thank you for inviting me to speak with you about the importance of risk assessment and its relationship to the mission of the U.S. Environmental Protection Agency. The EPA welcomes your concern and interest at this time. I would request that my written statement be included as part of the record.

As the EPA addresses risk assessment, we keep in mind several principles that have been articulated by Administrator Browner: the importance of using good science in environmental regulation, the need to address environmental justice and inequities, the need to create partnerships with States and local communities, the need to provide the flexibility required to achieve the standards that we all want, and the need to foster a sound economy.

We also share the goals of the President and Vice President to reinvent government so that it will work better for people.

In my testimony today I'll give you a brief overview of how the EPA approaches and uses risk assessment, as well as the steps that we're taking to continually improve our risk assessment process.

As Sally Katzen mentioned, the White House has convened an interagency working group to look broadly at risk policy issues, including risk-related provisions of various legislative proposals. The administration is hoping to develop more consistent approaches to risk analysis across Federal agencies responsible for protecting public health and the environment. The EPA is very involved in these efforts and I, in fact, will serve as a vice-chair of the risk assessment task force.

The Federal Government, including the EPA, has a long track record of using risk assessment to protect people. Since the 1950's, as the science has evolved, evermore sophisticated risk assessment schemes have been developed to assess the risks of pesticides and chemicals, not only to people, but now also to the environment.

A commonly asked question about risk assessment is why do we use animal testing data? The obvious answer is that we can't put humans at risk. The danger of using humans as guinea pigs is demonstrated by the case of asbestos-related disease in miners and the public outcry against the recent disclosure of the use of humans in radiation and chemical testing in the 1950's.

The development of a common risk assessment framework to assess cancer risks was enhanced by a 1983 National Academy of Sciences Report entitled "Risk Assessment in the Federal Government," also known as the Red Book.

In 1986 the EPA released a set of risk assessment guidelines dealing with cancer, mutations, chemical mixtures, risk during pregnancy, and how to assess exposures. Since the scientific basis of risk assessment is evolving, the methods we use should not be frozen in time. On the one hand, we're constantly learning about new health and environmental concerns. For example, we have the new concerns about environmental estrogen. On the other hand, research has led us to conclude that some laboratory evidence is not applicable to humans. Therefore, we need the flexibility to incorporate new science into our risk assessment methods.

As you've heard today, risk assessment is just a tool, and it allows us to neatly summarize a lot of complex scientific data. It makes our decisionmaking easier and more consistent, but to manage risks, we have to look at a number of other factors, such as societal expectations, economics, feasibility, equity, and other issues.

Some risk management decisions are based on different legislative paradigms, with which you are all familiar: the risk-based Clean Air Act, best available technology, as exemplified in the current Clean Water Act, and risk-benefit balancing contained in the FIFRA and TSCA. The policy choices are made by elected officials who represent the public with input from informed scientists and technicians. The public does not expect that technicians will actually make these decisions.

EPA develops numerous risk assessments every year, and I've brought some of these along to demonstrate how they range in complexity from relatively simple data requirements to more complex ones.

What I have here is something called a premarket notification under TSCA. We issue about 1,000 of these a year. You can see it's kind of skinny. This is a decision that actually industry likes because it allows industry, as they develop new chemicals, to be able to bring them to the market. Under TSCA, the enabling statute, we review these in 90 days and, with not a lot of data, are able to make a decision.

Similarly, I have a decision on a pesticide experimental use permit. This is a permit that allows a pesticide company to use the new pesticide in a field trial, which is a very important step in bringing a pesticide to the market. Again, it's a relatively skinny document.

Here I have a water quality criterion for ammonia and salt water. It's fatter. It's supported by several boxfulls of paper, but this is a rule that would have truly national significance.

And here, at the greatest extreme, is the air criteria document for ozone. This is a decision that affects every person in the country. We all breathe, and ozone is formed as a result of automobile emissions, and so this is based on shelf-feet and shelf-feet and shelf-feet of data, which are summarized in this little package here. It requires complex analysis because we're talking about decisions that affect the economy and all of our health.

EPA uses risks to set priorities. For example, in Administrator Browner's budget-planning process for fiscal year 1995, she had all of us look at ways to disinvest 15 percent in our lowest risk areas in our programs and to invest 15 percent in the highest risk areas. She also, along with the White House, identified substantial resources within the agency to address the problem of global climate change, which is a major risk that we have not been addressing, by cutting from areas of lower risk.

So within the discretion that we do have within the administration, I believe that we are trying to set priorities according to risk. Some would have EPA conduct more expensive risk assessments for everything we do in order to make better decisions. Allow me to describe to you the implications for EPA, the regulated community, and the public of developing a full-blown comprehensive risk assessment in support of every regulatory decision.

The implications for EPA would be that we would need to employ many additional highly graded scientific staff. There would not be commensurate improvement in our regulations, and routine decisions which now require a minimal amount of data would be delayed.

The implications for the industry would be enormous. First, there would be an enormous increase in data requirements and transaction decisions that are critically needed to do business, such as the experimental use permit and the premarket notification that I showed you.

Second, decisions with time value, like the experimental use permit, which needs to be timed to the growing season, could be delayed.

Finally, public health would not be better protected. It's really appropriate for us to put a commensurate amount of effort to look at risks into problems for the areas that are actually the most important for the public health.

EPA is continually working to improve our risk assessment approaches. We need to be clearer about our assumptions and models and when to depart from them. We need to address the unique risks of infants and children, and these are things that have been recommended to us by the National Academy of Sciences in this report entitled "Science and Judgement and Risk Assessment." It was released a couple of weeks ago, and it is a very comprehensive summary, not only of the state-of-the-art and what the agency does, but also the professional opinions of a mix of scientists who were involved in doing this assessment of what we could do to do a better job.

This report did support the notion that we should spend the most time on the most important hazards. As a doctor, the clearest analogy for me is how I would approach treating a patient. Every chest is not a heart attack. Every headache is not brain cancer. You start with a history and physical, and you order the tests that are needed. So it needs to be for assessing risks.

EPA is continuing to study this issue. We're providing funding for a $1 million study by the National Association of Public Administration to examine, among other things, risk assessment and resource distribution procedures at the EPA. And we are also helping to support a new National Academy of Sciences study to explore the issue of risk characterization.

We have also recently convened a senior level Science Policy Council, which is chaired by the Deputy Administrator Robert Sussman and vice-chaired by myself.

In conclusion, we appreciate the continuing interest of the Congress in risk assessment. EPA is serious about risk analysis. In fact, EPA has pioneered the use of risk analysis to protect public health and the environment.

I believe that we are in the forefront of risk assessment innovation. Although EPA agrees with the National Academy of Sciences that our basic approach to risk assessment is sound, given the state of science and data available, we also realize that we need to continually improve our practices in numerous ways. Thus, we welcome the White House process that we're participating in, to do that across the Federal Government.

Thank you again for asking me here to talk to you about this important subject.

[The prepared statement of Ms. Goldman follows:]

STATEMENT OF
LYNN GOLDMAN
ASSISTANT ADMINISTRATOR
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON ENVIRONMENT, ENERGY AND NATURAL RESOURCES
AND THE
SUBCOMMITTEE ON LEGISLATION AND NATIONAL SECURITY
COMMITTEE ON GOVERNMENT OPERATIONS

HOUSE OF REPRESENTATIVES

FEBRUARY 1, 1994

Mr. Chairmen and members of the Subcommittees:

I am pleased to have the opportunity to testify before you on the topic of risk assessment, on behalf of the Environmental Protection Agency (EPA).

As requested, Mr. Chairman, my testimony today covers the current use of risk assessment, comparative risk analysis, risk communication and cost/benefit analysis at the Agency, and the matter of potential legislation on the conduct of these analyses.

Definitions

It is helpful to keep in mind the distinctions among the various terms used in these discussions. I have provided below, definitions for *risk assessment, risk management, comparative risk assessment, risk communication,* and *cost benefit analysis* together with some perspectives on their appropriate application and their strengths and weaknesses.

EPA, like many other Federal agencies, has adopted the terminology of the National Academy of Sciences/National Research Council as provided in its 1983

report entitled "Risk Assessment in the Federal Government: Managing the Process" and reiterated in its recent report "Science and Judgement in Risk Assessment" (1994 NAS/NRC report). A major recommendation of the report was to distinguish the scientific assessment of risk from other elements of regulatory decision making (risk management) such as legislative requirements, technology feasibility, and social and economic impact analysis. This distinction ensures decision makers and the public that analysis and judgment of the nature and size of risk is governed by scientific principles and policies, and not prejudiced toward particular economic or social outcomes associated with regulatory decisions. As specifically pointed out in the 1994 report, this does not mean that there is not communication between risk assessors and risk managers about what the assessment of risk needs to address in order to support decisions. It also does not mean that risk assessment is the only science used in a management decision. Clearly the social sciences and engineering science, for example, contribute greatly to such decisions in terms of assessing the feasibility and acceptability of alternative policies.

Risk Assessment: Risk assessment is a set of tools used to summarize a body of scientific data to inform decisions. The NAS paradigm defines four elements of risk assessment: hazard assessment, dose-response assessment, exposure assessment, and risk characterization. Risk characterization is the presentation of scientific findings and their strengths and weaknesses so that decision makers can

understand and use the information effectively, along with other analyses supporting their decisions.

The bases of risk assessment are empirical data and analyses based on general scientific knowledge and accepted principles. These analyses do contain elements of judgment or inference. Technical judgments are based on scientific data such as amounts of intake of food, water, and air. Inferences are drawn about whether, for example, effects seen in animals may occur in humans. As noted in both 1983 and 1994 NAS/NRC reports, the process of risk assessment requires the use of scientific judgment and inferences to bridge gaps in our knowledge. This requirement suggests that, unless we have direct information on risk to exposed populations, we must use animal toxicology data and modeling techniques to estimate human risk.

A major point about assessments of environmental risks, both health and ecological, is that they result in characterizations and predictions about risk. The assessments are as strong or as limited as the quality and depth of data available. EPA's risk assessments are not meant to be estimates of true risk. They are in no way comparable to actuarial risk statements such as annual highway accident statistics. It is thus troubling and misleading when estimates are spoken of or used as though they were the same as actuarial risks. This makes it all the more important that the strengths and weaknesses of the assessment methods and data are explained carefully when the estimates are presented and when they are used. The 1994 NAS/NRC report recommends that EPA work much harder to make these

explanations clear and usable for risk managers, and we will be acting on this recommendation.

Science does not stand still. As more is learned about the biological effects of environmental contaminants generally and about effects and exposure to a particular contaminant, our risk assessment tools will be updated. At the present time our understanding of biological mechanisms or action of chemicals is growing rapidly. The development of the science of risk assessment must remain flexible in order to progress as knowledge of underlying phenomena improves. As progress occurs, risk estimates will change for individual contaminants. This will be disconcerting to those who have treated estimates as facts, but, in truth, should be understood as part of the evolution of the science and as adding to, not detracting from, the credibility of the science.

Risk Management: How the Agency conducts risk management is, by contrast, less consistent because of the different provisions of the statutes involved. Certain statutes may require EPA to conduct only part of a risk assessment such as the assessment of hazard (Is it a carcinogen under the Delaney clause?), or only an assessment of exposure (Is exposure widespread enough to require industry to perform toxicology tests?) or they may require a full risk assessment. Other statutes may require EPA to make a decision based only on risk assessment, or on hazard identification coupled with identification of best available control technology, or on a full risk assessment coupled with cost/benefit analysis. For example, the statutory findings for setting ambient air quality criteria for,

say, ozone are based solely on the elements of risk assessment; economic and technology analyses may be used only in considering ways to achieve the criteria, not in setting the criteria. On the other hand, emission standards for air toxics and effluent guidelines depend on hazard identification and analysis of available technology or feasible technology. In still another statutory construct, regulation of risk from existing chemicals under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires balancing risk reductions against economic impact of regulation and the risks of substitutes. There are numerous other statutory constructs governing regulatory decisions at EPA, requiring still other combinations of analyses. Regulatory risk management therefore has a very broad potential scope. Risk assessment is a component of varying contribution.

Comparative (relative) risk: The purpose of this kind of analysis is to set priorities. It asks the question, What are the most important environmental priorities? recognizing that limited resources need to be applied as rationally as possible to address the most important problems first. Risk assessment is only one piece of this exercise. Because knowledge, data available, and methods used to estimate risk on large numbers of risk problems are very uneven in scope and depth from one problem to the next, comparative risk analyses may be rudimentary and highly subjective as far as the science part goes. The outcome is a social policy analysis based on many complex social and economic choices. Nevertheless, the

Administration is committed to broadening the use of comparative risk analyses to help improve risk regulation.

Comparative risk analysis, in projects at EPA, has been used to describe related but quite different processes. The first is the exercise undertaken by EPA in its "Unfinished Business" report and subsequently extended by each EPA regional office, which involved ranking the health and ecological risks and the economic impacts (welfare effects) associated with the broad range of environmental problems that concern EPA. This work was reviewed by EPA's Science Advisory Board, which added additional perspectives to priorities, particularly in the ecological risk area, and recommended several improvements to the methods.

The second comparative risk process is one that is underway at the state and local government level with support from EPA. The goal of this work is to bridge science and public values so that consensus can be reached on future environmental directions at the state and local level. The work includes public involvement to define public expectations; a ranking of health, ecological and quality of life (economic and social impacts) risks; and a process for developing strategies for acting on agreed environmental priorities. A major project of this kind is underway in California, for example.

There are many areas of difficult judgment in a comparative risk analysis, some about science, but even more that engage other technical disciplines and social values. There are difficult balancing judgements to be made about issues

such as, for example, comparing the relative importance of species endangerment, groundwater contamination, and cancer risk from pollutant exposure. Issues such as environmental equity and economic impact, and public perceptions come into play at every step. Expectations of equity, economic benefit and use of environmental resources may vary widely. So, comparative risk assessment, while providing valuable information for policy makers, cannot substitute for the policy making process.

Each of these analyses may be important in making national decisions. It is, however, essential for the integrity of decision making to recognize their different purposes and ingredients. It would be misleading to advertise a comparative risk decision, for example, as being dictated solely by scientific principles.

Risk Communication: This communication occurs at many levels and for many purposes. The subject and its difficulties have given rise to a sizeable literature and a number of studies. The following remarks by Cohrssen and Covello[1], who have studied the subject for many years, capture many of its facets:

> Scientific information about health and environmental risks is communicated to the public through a variety of channels, ranging from warning labels on consumer products to public meetings involving representatives from government, industry, the media, and the general public. These communication efforts can be frustrating for both risk communicators and for the intended recipients of the information.... Government officials, industry representatives, and scientists often complain that laypeople do not accurately perceive and evaluate risk information. Representatives of citizen groups and individual citizens are often equally

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[1]Cohrssen, J.J. and Covello, V.T. (1989) Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks. United States Council on Environmental Quality. NTIS Order No. PB 89-137772.

frustrated, perceiving risk communicators and risk assessment experts to be uninterested in their concerns and unwilling to take to actions to solve seemingly straightforward health and environmental problems. In this context, the media often serve as transmitters and translators of risk information.... But the media have to be criticized for exaggerating risk and for emphasizing drama over scientific facts.

This quote is provided to illustrate the complexity of risk communication, which many here today have personally encountered. It also makes the point that risk communication is much broader than simply a thorough explanation of a risk assessment.

Cost/benefit analysis: As used under the Toxic Substances Control Act and the Federal Insecticide, Fungicide, and Rodenticide Act and Executive Order (EO) 12866, this is an analysis to compare costs and benefits of regulatory options, including that of no action, over time. Generally, benefits are more difficult to estimate than costs, although each element has uncertainties. Risk information is an input in terms of human health impact such as illnesses or deaths avoided or in terms of ecological harm avoided. Cost inputs include compliance costs (private and public) as well as the costs of not doing something else with the investment. The strengths and weaknesses of these analyses are a function of the quality, scope, and depth of the risk and cost information available and the assumptions made. Cost/benefit analysis is a tool that adds perspective to decision making along with other social and economic considerations.

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Risk Assessment is a Basic Tool, Broadly Used in Regulatory and Priority-Setting Work at EPA

For many years, the EPA has used risk assessment as one of the fundamental supports for its decision making. As pointed out under the discussion of risk management above, the application of risk assessment tools varies from statute to statute in accordance with legislative intent. EPA has been in existence for 24 years. In that time, it has acquired, piecemeal, a large number of statutory mandates across a very large number of environmental problems. If one looks back at this history, one can see a number of different paradigms for environmental decision making. In the first statutes, the aim was to define national criteria for clean air and water, broadly based on ubiquitous effects on public health and the environment, and to require states to take measures to meet the criteria. The next statutes were aimed at finding and nationally regulating unreasonable risks posed by sources or products to individuals and populations, considering cost/benefit analysis. The statutes that came next had regulatory schemes of various sorts including public health criteria in some, and technology-based criteria in others. Most recently, the Agency is expanding efforts in the area of pollution prevention which seeks to employ safer technologies and tries to reduce unwanted, harmful pollution. The result for EPA has been regulatory programs with different levels of flexibility and different risk and cost analyses to consider. Virtually every statute EPA administers requires findings about hazard or risk to be made in regulatory

decisions. Some statutory findings support decisions on criteria for allowable pollutant levels in the environment; findings of this kind typically call for criteria that prevent adverse effects on public health with an "adequate (or ample) margin of safety". Criteria for ubiquitous air pollutants such as ozone and for drinking water contaminants are of this kind. Other statutory findings support decisions on control of risks associated with production or use of commercial products including, for instance, package labeling requirements and restriction of allowable uses for the product; these findings typically call for prevention of "unreasonable risk" considering costs and benefits of regulation. There are other forms of statutory findings about hazard, exposure, or risk, supporting numerous other decisions. Findings using a range of terms such as "significant risk", "may present an unreasonable risk", "imminent hazard", "widespread exposure", prevent adverse effects with an "ample margin of safety" and others, are required to support decisions on clean up of contamination, listing of pollutants for regulation, identification of toxicity testing requirements, research priorities, reporting requirements, and many others.

It should be noted that required findings may rest on one or more components of a risk assessment or a full risk assessment. For instance, findings to support setting air quality criteria under the Clean Air Act (CAA) are based on hazard and dose-response components only, while many decisions on controlling uses of commercial products under TSCA or FIFRA are based on full risk assessments. As an additional example, requirements for industry to conduct

toxicity testing on chemical substances may be based solely on a finding of widespread exposure to the substances.

It is also instructive to note that while virtually all statutes administered by EPA require hazard or risk findings, only two require cost/benefit analysis, and some disallow consideration of such analysis in decisions. For example, TSCA and FIFRA are considered "cost/benefit" statutes. On the other hand, cost/benefit analysis may not lawfully be used in setting air quality criteria under the Clean Air Act or drinking water contaminant levels under the Safe Drinking Water Act.

The President in EO 12866 has broadly incorporated risk assessment into Executive Branch decision making, consistent with existing law. This order directs that "[i]n setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction." The order also requires each agency to base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for and consequences of the intended regulation. Considerations such as flexibility, government cost of enforcement and compliance, and distributive impacts and equity are to be included.

It is fair to say that analyses of risk or its components are an essential and everyday part of the business of the EPA, as are cost and technology analyses. These analyses are conducted not only for making statutory findings, but also routinely as a basis for program managers to decide how to allocate the resources available to conduct their work. In my own office, and the other EPA program

offices, we must assign our staff and appropriated funds to work that has the most importance for public health and the environment. It is always the case that the agenda of potential work extends beyond the resources available; we use analyses of potential risk to make the necessary decisions about priorities for investment of resources. For example, Administrator Browner employed such considerations in allocating budget resources for 1994 and in making recommendations about 1995. Many of these are screening analyses that are of a limited scope and depth. They are done only to a level of analysis that tells us which problems should be on the agenda and should have further investment. This process is iterative and is a process recognized and recommended in the NAS/NRC report.

It is worth noting here that we provide the results of our analyses to state and local environmental and health agencies for their use. We also conduct analyses at the request of these agencies, or as joint exercises, or they provide their work for our consideration. The communication in this regard is systematic and continuous. For example , the EPA information data base: "Integrated Risk Information System" (IRIS) contains agency scientific staff consensus assessments of hazard and dose-response data on over 600 substances. IRIS is available on-line through the National Library of Medicine nationwide computer link and is available and used internationally as well. Another example is day to day technical assistance such as that provided through the AirRisc technical assistance program operated by the Office of Air and Radiation and the Office of Research and

Development at EPA, which responded to approximately 600 inquiries in 1993. The state and local agencies also have statutory risk findings to make and their program managers must allocate resources. The practices of risk assessment are their daily work just as they are for the EPA. There is a national community of risk assessors as well as an international one.

For the future, I foresee no change in the status of risk assessment as a fundamental part of all of our activities. There is also no question that the methods and scientific basis of risk assessment will change and improve, as they have in the two decades of EPA's existence. In this regard the NAS/NRC report "Science and Judgment in Risk Assessment" will play an important role. While the report was mandated by the Congress under Section 112 of the Clean Air Act to particularly address the assessment of risks associated with exposure to hazardous air pollutants, it also applies to the conduct of risk assessment generally. The report points to changes that will improve current risk assessment practices, to basic research that will improve the science in the long run, and to near term technical developments that should be supported. The EPA's newly chartered Science Policy Council, which is chaired by the Deputy Administrator, and for which I serve as Vice-Chair, has been charged to plan activities for improving risk assessment methods in view of the recommendations of the report. Our view is that the methods of conducting risk assessments must change continually to incorporate new knowledge gained from basic research and, accordingly, guidance

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for conducting risk assessments must not become a set of inflexible rules. We are encouraged in that view explicitly by the NAS/NRC report.

Advisability of Legislation

I hope that I have made it clear that EPA favors and extensively uses the tools of risk assessment, comparative risk assessment and the other analyses discussed. Reservations I will express about general legislation on these subjects should not leave any impression to the contrary. My concern is that the tools we have must be allowed to be used flexibly and constructively, and that our resources must be used productively.

The following quotation is taken from the NAS/NRC report; it says on page E-14: **"Risk assessment is a set of tools, not an end in itself. The limited resources available should be spent to generate information that helps risk managers to choose the best possible course of action among the available options."** This quotation is worth keeping in mind.

I am concerned that the aim of sorting out national priorities and changing the considerations used in risk decisions uniformly cannot be achieved by simply improving risk assessments, or even by just requiring certain analyses in all decisions. The effect would be to drain the resources and time of EPA programs into performing analyses that are inconsistent with existing statutes and to cause confusion about which decisions are science based, and which are not. A program manager at EPA must have some discretion to rank priorities within his or her program, but there is often a statutory list of pollutants that must be regulated on

a defined schedule with little or no discretion to decide, or take the advice of an advisory committee, that an individual pollutant does not present a risk that justifies regulation.

The fact is that existing statutes with mandatory actions and schedules and findings will continue to drive the agenda and the stringency of action. One example will suffice. An ambient air quality criterion for ozone is set under the Clean Air Act by judging the health impact associated with exposure as revealed by a risk assessment. What would be the role of a comparative risk assessment comparing highway accident statistics, or other commonly encountered non-environmental risks, or comparing another environmental risk to ozone? Some role would be implied, but currently such analyses cannot be considered in setting the criterion. The potential cost and time required for performing the analyses would be large, and the questions of whether they were adequately done and were intended by Congress as simply informational exercises or were to be used in some way in decisions would inevitably be raised. I believe that the Congress performed comparative assessment of national priorities in constructing the statutes EPA and other agencies administer, and continues to apply such judgment in oversight. As previously discussed in this statement, comparative risk assessment is a risk management tool that depends as much, or more, on judgment about social values as it does on any technical analysis. This is an appropriate role of oversight. Legislation about the analyses and considerations the EPA should use in its

decisions should be specific to the statute being examined, in the context of the relative importance of the work to the public, as Congress views it.

A great concern with legislation requiring rote use of various analyses in every decision is that the EPA would have to take many of its already over-committed and limited staff of technical experts off their work of performing scientific and engineering analyses and economic analyses in support of EPA decisions and devote their time instead to producing more documents. In the case of the Johnston amendment, either a substantial number of new FTEs or a substantial amount of existing staff time would be required to make comparative risk documents for every rule. If the latter, these staff would necessarily have to be the same experienced staff who are currently working on statutory responsibilities such as safe drinking water standards or pesticide registration. None of these jobs could be done by inexperienced new hires. In dollar terms the cost would be $10 to $35 million in additional dollars per year, similarly subtracted from support of Agency decision making efforts. In large part, the documents would either not be part of the findings required by the statutes under which decisions are made, or are analyses that under current law would not be considered in the decisions. In such cases they would be information documents. Because the experts involved in creating the analyses needed for decision making would be required to, instead, devote time to these information reports, the schedules established for rule making and other actions under many statutes would have to be extended. To the extent the analyses called for are part of Agency

decisions, they are already being done, explained in the Federal Register, and placed in the public docket.

As another example of the result of rote exercises, in many cases the cost of performing a cost/benefit analysis based on a risk assessment would exceed the cost of complying with the rule in question. The average cost of such an analysis ranges from approximately $200,000 to $2.3 million. For a recent rule requiring that all plastic beverage-container rings be degradable, the cost of analysis would have exceeded the impact of the rule because all three U.S. manufacturers were already making degradable rings. Similarly, the compliance cost of a Significant New Use reporting rule under TSCA is about $5,000, a small per cent of the cost of analysis. As a third example, the estimated "cost" of a rule under development to prevent evaporation of solvents from cleaning baths for industrial parts is a savings of about $30 million to industry nationwide. The cost of the cost/benefit analysis would thus reduce the national savings realized. There are many other examples of this kind that could be given. They illustrate that rote application of analysis would be less than productive.

Legislation that imposes requirements for the conduct of scientific analysis in risk assessment inherently carries the danger of freezing the progress of the science. Whether the outcome will make sense when viewed in the context of the state of science in 10 or 15 years is questionable. Views of the role of risk assessment may change also. The science of risk assessment is young and developing; it develops by assimilating new learning from the basic sciences and

changes in an iterative fashion, replacing old methods with improved ones. If this development is taken out of the hands of scientists and put into the hands of courts trying to interpret the terms of legislation, the components of risk assessment will inevitably acquire legal definitions as opposed to scientific definitions. This will freeze the science by making change impossible in the absence of new law.

The issue of what analyses the EPA currently conducts and the resources it has for the purpose will be the subject of a congressionally mandated study being performed this year. The Congress has allocated 1994 funds to a study by the National Academy of Public Administration. The appropriations committee report lists the following to be studied: (1) Risk assessment and resource distribution procedures at EPA, including methodologies, collection, and incorporation data and peer review processes; (2) risk characterization processes, including the handling of scientific uncertainties, the generation of assumptions, and the determination of priorities; (3) comparative risk analysis procedures and their relationships to the assignment of priorities and the allocation of resources; (4) alternative decision making models and their potential utility in conjunction with the risk assessment approach; (5) EPA organizational structure, staffing patterns and internal management systems, including regional and field office activities; and (6) impacts of relevant legislative authorities and congressional oversight mechanisms on program priorities and resource utilization.

Before concluding I want to note that the Administration opposes all policy amendments to the legislation elevating EPA to a Cabinet Department. The bill should focus exclusively on organizational and structural matters. Consequently, the Administration opposes the Johnston amendment to the Cabinet bill.

Conclusion

EPA appreciates the continuing interest of the Congress in risk assessment. Because the EPA uses this tool very broadly for risk-based decisions and priority-setting we believe that its appropriate use and place in carrying out Congressional mandates are appropriate subjects of oversight. The new EO 12866 on regulatory development and review articulates this Administration's serious commitment to risk assessment in regulatory development. OMB currently is developing agency-specific guidance on the EO's implementation and has started a dialogue with affected stakeholders. EPA intends to continue to use risk assessment and the other analyses that assist decision making and to work continuously to improve their technical quality.

Mr. Chairman, that completes my prepared remarks; I would be pleased to answer any questions the Subcommittees may have.

Mr. CONDIT. Thank you, Dr. Goldman. We appreciate you being here this morning.

Mr. Hirl's testimony in the previous panel quoted you as saying, "Hurdles for incorporating more science into risk assessment practices have become absurd." Is this an accurate quote? And if so, would you expand on the quote and kind of let us know what you meant by that?

Dr. GOLDMAN. I do not believe that the problem is incorporating the scientific data. The problem has been the problem with our being able to keep our guidelines up to date with the science. I think the last time that the cancer guidelines were updated was in 1986. What's happened since then is there's been a form of gridlock within the EPA in being able to take in results of new research and redo the cancer guidelines.

I think one of the jobs of the new Science Policy Council is going to be to insist that on a regular basis, that we revisit our policies and update them.

Now, there will never be a world in which a policy that we have will be totally up to date with the science, because the minute I write down a policy, another study is going to come out in the scientific literature that I'll want to incorporate. But we must have a process whereby on a regular basis, we incorporate the new science, and that has not been the way that the agency has done this. Each revision has been ad hoc, and there hasn't been an insistence that, on a regular basis, this be done.

Mr. CONDIT. Thank you for clarifying that quote. I appreciate that. I asked this question earlier and I want to pose it to you. If the Johnston amendment were amended to include only those regulations that have an impact of $100 million or more, how much would it reduce the cost of compliance? Has the agency done any calculations on this matter?

Dr. GOLDMAN. We haven't done any calculations, but I think that it would have a different impact than the impact of the Executive order. For example, a premarket notification, which was one of my examples, certainly in terms of the company involved, might go over the $100 million cut, but we would still feel that we don't need to do a complete risk analysis for that kind of a notification under the Executive order.

If we were only looking at a $100 million cut, then we would probably have to do some additional analyses in areas that we don't have to do them now.

Mr. CONDIT. I took Senator Johnston, by his comments this morning, that he's open for negotiations on what regulations should be imposed and what shouldn't, what should be risk assessment, what shouldn't. Did you understand it that way, and would that make a difference in the EPA's approach to his amendment if he's willing to do that?

Dr. GOLDMAN. Well, in the context of the Cabinet bill, the position of the administration is that we are opposed to this amendment or any form of this amendment.

Mr. CONDIT. How about a freestanding bill that complies with the intent of the Executive order?

Dr. GOLDMAN. I can't comment until I see the bill, but I think that certainly the idea that you have put forth in terms of attempt-

ing to craft a bill that reaches that intent is something that we're willing to work with you on.

Mr. CONDIT. Mrs. Thurman.

Mrs. THURMAN. Thank you, Mr. Chairman.

Dr. Goldman, just so you'll know, when you're out looking for questions and talking to people, have a high regard for at least the pesticide area, which I guess you're in kind of control of. So they feel like you've used a lot of these kinds of things.

However, and I think I heard you say that you had put together a Science Advisory Board or some kind of a board?

Dr. GOLDMAN. Science Policy Council.

Mrs. THURMAN. Is that not like reinventing the wheel or something that was done, I believe it was called the Science Advisory Board back in 1990?

Dr. GOLDMAN. The Science Advisory Board is a group of external scientific advisers. There is an executive committee and a number of subcommittees, and they do extensive peer review of the work that the agency is doing.

The Science Policy Council is an internal group, chaired by the Deputy Administrator, vice-chaired by me, with a number of high level individuals. It's there to set the policy and to give Administrator Browner policy advice about the direction that the agency should be going.

Mrs. THURMAN. But they kind of did that, too. They made recommendations, I believe, using risk-based priorities. I mean, they listed risks. Have those been incorporated in your discussions with the group that you're working with?

Dr. GOLDMAN. Yes, they have, and in fact, we have a formal relationship between the Science Policy Council and the Science Advisory Board. The head staff person of the Science Advisory Board, Donald Barnes, serves as an ex officio member of the council, as does Administrator Browner's science adviser, William Raub.

What we've attempted to do is link these. One of the roles of the council will be to make sure that thorny issues on which we need external comment are brought before the Science Advisory Board, and also that the recommendations that they give back are really translated into action and that the agency is accountable for following through with new science policies.

Mrs. THURMAN. Since the Executive order has been in place, can you give us any examples of where, in your department, that you've actually used the tools that were recommended by the Executive order?

Dr. GOLDMAN. Actually I can, and I think that this is good because one, I think that the Executive order goes well beyond the issue of just risk assessment. The Executive order actually gets into the area of trying to streamline and make government regulation more meaningful, instead of just regulations, one on top of the other, trying to set priorities that are based on risk, trying to take into account the needs of the States and locals and tribes.

There are many examples. One that I can certainly use from my program on the TSCA side, is that we have received a petition related to an issue that is of great concern for one of the States. I can't say a lot about it at this point because it's under way. But we have been able to involve the State on the work group, in look-

ing at the petition and in developing the decision that I will have to make about the petition. This is something that traditionally has not been done in the agency, bringing the States in upfront, for issues that critically involve them.

Another place, which was a rule that was actually well under way before I got here was with the expansion of the toxic release inventory [TRI], where, in the process of working with the Office of Management and Budget, Sally Katzen and I realized that while we were proposing to expand the TRI by adding a lot more chemicals, we were not paying attention to some of the issues about places where the reporting may not be providing us with very much benefit, and that even the relatively small burden of reporting may be excessive, compared with the benefits that we're getting from that.

So in the middle of this month first, we changed the proposed rule to say that we're going to look at that issue. Second, in the middle of the month we'll be holding a workshop where we bring small business, the environmental community, various others in States also who are concerned about TRI to look at what the alternatives might be for reducing the burden on small reporters or even people who are reporting zero emissions, which right now must be reported, and what the tradeoff there is—how much information will be lost by various cuts, and hopefully to develop a kind of consensus about where we can go to unburden that community.

Mrs. THURMAN. One of the comments that you made strikes me as being interesting, particularly because it seems that industry is very supportive of doing risk assessment and cost-benefit analysis. Do you see this causing them more problems than benefits? Maybe you're not the right person to ask, but what I don't understand is why, then, does it seem that industry is very supportive of an issue like this, versus what you're saying?

Dr. GOLDMAN. I think this is an example of why we have to have a dialog about these issues among all of us because I think that often what people focus on as being broken are the things where they've had a problem. I would have liked to have heard more of the specifics of where the problems really were, as you asked, because I think that that helps us key in on what is broken.

I think there are many other things that we do that are not broken and that people don't perceive as a problem. For example, I think the premarket notification system is not perceived by industry as a problem, and if, in the process of fixing something else, we break them, then that's not good government. We're just layering on another requirement that is not going to help us function better.

Mrs. THURMAN. Dr. Goldman, the other thing is, and I think that Mr. Condit and probably several of us agree on this is that the Executive order is only as good as the administration. If this administration believes it's a good tool that should be incorporated and that we should be using these tools, why is it so wrong to try to put it in the law?

Dr. GOLDMAN. Well, to answer that question, maybe an analogy might help. One of the laws that I'm wrestling with the most, the Delaney amendment to the Federal Food, Drug, and Cosmetic Act which, when passed in the 1950's, probably looked imminently reasonable. In fact, it was a couple of years after I was born that it

was passed, and it probably looked very reasonable at that time because we didn't have good ways of measuring residues, and we also didn't have very good ways of being able to protect people from risk by controlling exposure, as we do now.

So the goal of zero probably seemed like a very reasonable way to regulate carcinogens and food at that time. I think that when we specify in the law things that seem to us to be imminently reasonable now, we have to keep it mind it can be very difficult to go back and change those laws, because when you change, there are winners and losers involved.

That's why I would rather, and this is really more personal, but I'd rather not see issues that involve science frozen in the law, even in the ways that we may not realize at this time that we're doing that.

Mrs. THURMAN. But doesn't an Executive order do that to you as an agency or department already, kind of freeze that in for you?

Dr. GOLDMAN. Well, an Executive order can be changed with considerably less process. Now, one of the interesting things that Sally Katzen has pointed out to me is that since President Nixon, we have had Executive orders related to risk analysis. When you look at the evolution of those with successive administrations coming from different political points of view, you see a gradual evolution. You don't see vast swings. There may have been changes in how things were actually implemented.

I think that the Executive order, as a procedure, does give the flexibility to be able to change when there are major changes. I believe if the Delaney amendment had been done as an Executive order back in 1953 that it would not be the law at this time.

Mrs. THURMAN. Can I ask one more question? And I'm real queazy to ask this because it's an assumption being made by me and it's hearsay and it really has nothing to do with you, in essence.

But in my district there's a problem that's been going on and there's a court case. The impact was big to the community.

So there is conversation from outside groups that are watching what government does and that group of people sometimes believes that maybe if we did some cost benefit or risk assessments that maybe some departments and agencies wouldn't just be solving cases or trying to cut through court cases but then just kind of lending to a few people, versus a whole community. I hope I'm making sense.

And that, in fact, has happened, where we can actually see some regulation that's been developed in that area because of a court case. They don't look at anything other than just trying to appease a group of people.

Do you see that? I mean, how do we stop those kinds of things? I think that's part of the process here, and that's why the tools are so important, is to be able to clarify all of these kinds of things.

Dr. GOLDMAN. I'm not sure exactly what you're referring to in terms of the specific case, but I'm taking it that the general question you're asking is about settlements that are reached in the process of litigation and whether these settlements sometimes have impacts that are well beyond the litigation, and in essence, end up——

Mrs. THURMAN. More so it doesn't go to litigation. They just kind of settle it and without taking a lot of the other variables into account. They come up with rules and regulations that just answer their questions and go on their way.

So the case never goes and the people that are being impacted by it or, in fact, would be the ones that would have to carry out this, feel harmed and have no ability to get in there and change it.

Dr. GOLDMAN. Yes. I think that we would agree that we need to have tools other than some of the traditional tools that have been used—for example, litigation—to get us where we want to go and to redress the concerns that people have in local communities.

Without being able to comment about the specific situation, I think that's one of the things that we're trying to do with the reauthorizations that we're working on. With the Superfund reauthorization, we are trying to get more involvement of the local community and more attention being paid to what is the use that the land is going to be turned to for that community, to benefit that community and what's appropriate for that use. This is opposed to the way that we have traditionally done this, which is to try to do everything the same in every community, as though every community were going to do these things in the same way, and where these things have tended to go down the path of litigation instead of action.

Likewise, I believe, with the Clean Water Act, we are trying to take more of an ecosystem-based approach, instead of just going for the same technology for everywhere, no matter what the local circumstances. We want to try to look at the ecosystem as a whole and what's the most cost-effective way to fix the problems in that area.

Those are the kinds of tools that we're striving to have as an agency, to get us out of the way that we're getting things done is through these kinds of litigation techniques, when the things that we're doing don't make sense for everybody and every community.

Mr. CONDIT. Ms. Brown.

Ms. BROWN. Thank you. Dr. Goldman, you heard a lot of what the experts on the previous panel had to say. And in fact, I mentioned to Congresswoman Thurman particularly the college professors, and she mentioned to me that I was one for 16 years, but are there any particular points that you would like to make, responding to the previous panel?

Dr. GOLDMAN. Not really. I felt that they all, as Judge Breyer said, generally agreed, as we would agree, that these tools for assessing risk and for assessing benefits and costs are good tools. I think they all agree that they should be appropriately applied.

I think they all agreed that we need to be able to set priorities. We need to put our resources where we can get the most marginal benefit from the expenditure of those resources. And I didn't say to the greatest risks, because I think you do have to do that weighing of where you can get the most impact. I think that's the process that we're all engaged in. Certainly the exercises here on the board in front of you—the public survey, the survey of the EPA experts, that's a way to start getting at it. What's relatively more important

and where should we be putting our resources? I think we're in basic agreement on that.

I think that where the rub is: how do you do that? And where we see the biggest bang being within the authorizing statutes that really set the mandates that we have. If there are State and local mandates, they come from those statutes. We want to work with State and local government and with Congress to, as we go through these reauthorizations, work out ways to carry out those programs in ways that make more sense.

Ms. BROWN. How many risk assessments does EPA perform in a year's time? Can you give us some——

Dr. GOLDMAN. I'm not even sure what the number is. I'm really not sure. A lot.

Ms. BROWN. Can you give me an estimate, a range?

Dr. GOLDMAN. Literally hundreds. We literally do hundreds a year.

Ms. BROWN. My last question, and I know you can't answer it but I'm going to ask it anyway. If the bill arrives on the President's desk with the risk assessment language, do you think—someone asked earlier—do you think he would take out his veto pen? I think the elevation bill is very important, but if it comes with a lot of baggage, even though it's well intentioned, what do you think he's going to do?

Dr. GOLDMAN. I cannot second guess the President on this, but the President has made it very clear to us that he wants a clean Cabinet bill, and he does not want a bill burdened down with these kinds of requirements.

Mrs. THURMAN. If the gentlewoman from Florida would yield?

Ms. BROWN. I yield.

Mr. CONDIT. Mrs. Thurman.

Mrs. THURMAN. So then, to carry that a step further, if we were to put his Executive order into law, with some fine-tuning. I mean, all of us up here who have worked with this issue have been willing to sit down and compromise. It seems like it's quite the opposite. Nobody will sit down and tell us where the real problems are with this, and yet it's in the Executive order.

In your opinion—we'll make that very clear—do you think that if we were to take the Executive order, with whatever flexibility was necessary, in a piece of legislation, to put it in law, we would have this same battle going on?

Dr. GOLDMAN. As a separate law, I can't speak on behalf of the administration about the position, but I can say that we're willing to sit down with you and work on it.

Mrs. THURMAN. OK.

Mr. CONDIT. Ms. Brown, are you finished? Thank you. Mr. Mica.

Mr. MICA. Thank you. Ms. Goldman, I guess I'm to infer from the comments in response to the question by my colleague from Florida, Mrs. Thurman, that the administration doesn't have any legislative proposal dealing with this subject that they plan to present to the House or Senate or the Congress at any time in the near future?

Dr. GOLDMAN. Other than the individual reauthorizations that we are working on—the Clean Water Act, Safe Drinking Water Act and Superfund—we don't. Now, within each one of those, there is

a considerable amount of attention being paid, not only to the issues of risk but also the issue of unfunded State and local mandates.

Mr. MICA. Well, in my opening comments I made reference to the impending Waterloos that are going to occur at each of these junctures, as we take up Clean Air, Clean Water, Superfund.

Wouldn't it be wise for the administration to work with the Congress at this juncture, when we have an opportunity and a vehicle here, to address the problem legislatively, give you the authority that you need, that does do the things that need to be addressed?

Someone asked the question: Does the President have the authority? And I repeated that: Does the President have the authority?

Quite frankly, when I heard Bennett Johnston go through the Executive order—I'm not an attorney—but you all don't have the authority to deal with this with any better handle than we've had up to date, and he confirmed that. Others have confirmed that.

So why not come and be a constructive partner with us and look for a resolution that could also be a model for these other junctures, which you know you're going to come to within this agency, and then we might resolve the problem, too, for the larger Federal bureaucracy?

Dr. GOLDMAN. Well, we are here to work with you and I think that the issue here is that we do not think that the first choice is the bill on risk assessment. The position of the administration has been that the Executive order is procedurally the best way to go in terms of addressing the issue, and that we have felt very strongly that even if we have a bill on risk assessment, that that will not obviate all of the requirements in the specific statutes under which we work.

So, I believe that if people are concerned about the impacts of the Clean Water Act, the Drinking Water Act, Superfund, that's where we need to work on those issues, because even if we have a bill saying that we'll do 10 times more analysis of the cost and risk and the benefits, if the bills still dictate certain courses of action, we will take those actions.

So I think the core of the problem here really is the problem of the burdens on State and local government and the need of the Federal Government to address those burdens. We need to address them in the authorizing legislation. We also need to address them in the culture of the agency and how we work, and I think the Executive order does that.

Certainly when the President tells me I should do something, I'm going to do it, and I'm going to make sure that my people do it.

And that's where we would like to work with you. I mean, let's see what's broke here and work together to fix it.

Mr. MICA. Well, there seems to be a commonality that it is broke, that we do need to address it, with almost unanimous consensus that we need to address this legislatively. And then we have the record, not only of the past administrations, but just the past year. And while the agency says one thing, that they're working toward utilizing risk assessment, a cost-benefit approach, they do something else.

As recently as January 24, you issued a ruling requiring that for the first time, large canisters on automobiles to capture smog-producing emissions that currently escape into the air when people fill up their gas. And this action flies in the face of congressional testimony of November 2, 1990, during the debate on the Clean Air Act, that said that the health benefits of automobile on-board canisters would be inconsequential.

So we have, just within the last week, seen actions that don't meet with the intent and comments. You know, you're talking the talk but we're getting different action from the agency. So now we'll deal with this particular situation that hasn't, I don't feel, been addressed with the criteria we're talking about.

So even with the good intentions, with the Executive order, I don't see us making much progress. Would you like to respond?

Dr. GOLDMAN. Certainly. I think the canister rule, the proposal, does look not only at risk assessment but also a cost-benefit considerations, and I think that the proposal strongly argues that this will be an extremely beneficial action for the costs that are required.

Now, this is an example of the way that the administrative procedures do work. This will be proposed. It will be published. There will be a chance for comment. There may be people who will come forward, as somebody did in testimony to you, to say that it's not worth it, and we'll have to consider that. But even with a law saying you will do risk assessment, you will do risk analysis, I don't believe we would have done much more for that proposal than we actually did.

So even with that kind of an analysis, people of good will may end up disagreeing, and we are not going to solve that problem. After looking at all those issues, everybody may not agree. But I do think that under the Executive order that we are able to unfold what the factors are that went into that analysis and let anybody see it. If they have objections and disagree, they can bring forward their arguments and if the agency was wrong and OIRA was wrong in its review, then we may need to reconsider it. I think that's the point of how we're trying to do business here.

Mr. MICA. Well finally, and I don't mean to belabor the point, but you have many directives from Congress in the face of laws which the agency is responsible for enforcing. Don't you think, though, that in the face of this plethora of laws, that with just the good intentions of the agency, which so far I may question, and an Executive order without any teeth, that we, in fact, are not going to make any progress on this, that for some reason, somewhere in the bowels of the White House or EPA, they fear that having statutory authority to do their job is a threat?

You said the Johnston amendment might freeze programs of science. We're not asking that there be any freeze. Actually, we're looking for sort of a continuum of an approach that does assess progress in science and other factors that should be taken into account. So again, my question is do you still deny wanting the legislative authority?

Dr. GOLDMAN. I do not deny that Executive order is not enough, and that's why we're coming to you with four major reauthorizations during this session, which I think has been an incredible

amount of labor and effort on the part of the agency. I think that we recognize that in most of the areas where we operate, that we need different kinds of authorities than the authorities that we have, and especially that we need to be able to address the needs for the kinds of flexibility, to take care of the needs of State and local government.

A law on risk assessment won't do that. We really need to look at that in the context of the authorizing statutes that provide the mandates that we operate under. That's why we're putting so much effort into crafting these reauthorizations.

Mr. MICA. Thank you. Mr. Chairman, I will conclude and also ask unanimous consent to submit some specific technical questions for the record, if I may. Also, I couldn't let the hearing conclude today without taking just a moment to say how much I appreciate your leadership on this issue, Mr. Condit, and also my colleague from Florida, Karen Thurman.

This is an important issue to the Congress and to the American people and to local and State governments and business and industry and agriculture, and your leadership has provided this forum today and also kept this topic where it should be—debated in the Congress and hopefully resolved by the Congress. I thank you both.

Mrs. THURMAN. I'd like to be associated with those remarks, but will include Mr. Mica's name, versus my name.

Mr. CONDIT. Thank you, Mrs. Thurman. Without objection, your questions will be submitted for the record, Mr. Mica.

[The material can be found in the appendix.]

Mr. CONDIT. I would just like to ask one question. Would you feel comfortable, Dr. Goldman, if the environmental laws of this country were done by Executive order?

Dr. GOLDMAN. No, I would not.

Mr. CONDIT. OK. Well, why?

Dr. GOLDMAN. Because I don't think that in essence, the environmental laws should be about technicians within my agency, the White House, other places in government looking at science, economics, and writing the laws.

I think that the process that you can carry out best, in terms of serving the public interest, has to be a part of producing those laws.

Mr. CONDIT. Could you just flip that answer and do the same thing with risk assessment?

Dr. GOLDMAN. To me, risk assessment is merely a tool that we use to manage. I do think that it is appropriate for the executive branch to issue Executive orders about how to manage our business and that it's certainly appropriate for the President to tell all the agencies in government how he wants us to write our regulations and how he wants us to manage.

Mr. CONDIT. Dr. Goldman, thank you very much for your time and your patience. We appreciate you being here and we commit to work with you and Ms. Browner to develop some of the suggestions we made this morning. Thank you very much.

[Whereupon, at 2:10 p.m., the subcommittees adjourned, to reconvene subject to the call of the Chair.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

MANUFACTURERS COUNCIL
of the CENTRAL VALLEY

February 1, 1994

The Honorable Mike Synar
Chairman, Joint Subcommittee
Environment, Energy & Natural Resources,
and National Security
Committee on Government Operations
2157 Rayburn House Office Bldg.
Washington, DC 20515-6143

c/o The Honorable Gary A. Condit
Congressman, 18th District
California

Dear Congressman:

The Manufacturers Council in the Central Valley of California represents 59 native and multi-national companies with over 80 facilities employing approximately 65,000 employees. Our Council's focus is to address issues affecting the quality of the environment while ensuring economic stability in our region.

We appreciate the opportunity to comment on the issue of risk assessment. This is a necessary process for evaluating what, where and how resources should be directed toward protecting our environment. While comprehensive, it creates an opportunity for decision makers to holistically approach the criteria for evaluating the environment in order to choose alternatives with specific limits based upon realistic standards, and requirements which are finite and measurable. Choosing any alternative must have with it the element of risk. You are here to decide the process for accurately assessing all of the risk, while minimizing the assumptions. In doing so, the outcome will be to control the probability of occurrence in our environment, while limiting the consequences.

Balance is always the proof of any good decision, and our process for determining balance must have risks and opportunities in the evaluation. Case in point: An operation producing canned vegetables is assumed in violation for recycling treated water to a river at five degrees elevated temperature. The prohibitive regulation determines the need for cooling exchange to reduce the temperature to within regulatory specs. Hence, active metals are introduced to the water stream from a heat exchange unit and air particulate from cooling towers are introduced from the same system, while at an exorbitant cost to the producer. The producer is now confronted with air borne risk contaminants and the right-to-know requirements for the general public. This creates significant costs for administering and the potential for public litigation, depending on the situation.

P.O. BOX 1564, MODESTO, CA 95353 · (209) ~~526-4240~~ 577-3158 / FAX (209) 549-0389

There is not a process for evaluating the balance of choices to be made, only compliance. Assumption: significant amounts of biological species are at risk due to the introduction of water at elevated temperatures for miles downstream and an ecosystem may be destroyed in time. Reality: tide pools on the same river create identical temperature patterns that are normal to the ecosystem.

This kind of compliance in our regulatory system is prevalent and complex and does not provide for a process approach to resolving what is at risk in our environment. If the process of evaluation is to have all of the necessary components comprised in each alternative, then public comment must and should be a part of the process. This is a very necessary part of providing the balance in assessing the risk component. If nothing else it, provides technical information for use in the cost analysis feature of the assessment. In working with regulated businesses nationwide over the last two decades, especially in California, there has been a very narrow-minded attitude of distrust in dealing with companies providing any input in the environmental arena. Today, many businesses are more "environmentally conscious" then the protected public, and do a better job of protecting the public against itself on environmental issues.

"Assumptions used to arrive at the characterization of particular risks" must be allowed to withstand, like any other hypothesis, the scrutiny of inquiry in order to draw out the concerns that would be addressed in comparative analysis. A private sector advisory group should comment on the sectors which may be impacted by such an analysis, and solicit the necessary input on such an evaluation. Trade and regional business organizations would be a logical area to employ such considerations.

Too often the consideration of employing regulation is in the interest of time and not the benefit of well funded research. Case in point: Current development of particulate matter(PM-10) standards in non-attainment areas where completion and consideration based on research (consuming millions of dollars) WILL be fruitless. At an early point in the process there needs to be a mechanism for development of the criteria with outside input used in formulating the basis for that criteria. It may be research, or experiential input, but it must be integrated into the risk evaluation formula. This is what ensures adequacy in "reasoned decision making".

The approach of comparative risk is a critical ingredient in keeping the "conservative" standardized assumptions in perspective. It does not seem, for instance, that the "scientific uncertainty" associated with a sector of "criteria pollutants" is valid in protecting the general public in an area where the risk of a fatal gun shot wound is in the parts per thousand, when compared to the carcinogenic risk in the parts per hundred thousand. It demands of society what priorities there should be in acquiring resources to get the job done! Yes, there is a critical link here. Fees pay to regulate pollutants, and, fees pay to regulate crime, but only one source contributes the lion share of the kitty, the regulated businesses in the community.

Our Council has faced an onslaught of regulatory statutes in the past five years and it is sucking the life out of these companies. Technical compliance features in the statutes are becoming catch alls for the medium and small businesses. Interpretation of the science of risk in compliance organizations is in an all time frenzy. Responsible discretion of compliance staff is completely unpredictable and companies are forced to defer or shelve 3 to 5 year planning cycles. Large bureaucratic regulatory agencies show little or no integrated assessment of "comparative" risks from water to soil to air. Case in point: In 14 months medium and large sized facilities have had to comply with four different risk management statutes. Toxic hot spots(air quality); Risk Analysis of acutely hazardous substances(liquids/RMP);Process Safety Management(job site exposure); SARA Title III implementation(materials catch-all/solid, liquid, air; and on a projected two year cycle ARP. All of these regulations are intended to control the probability of events and ongoing levels of exposure for the same substances. Is there accurate cost impact assumptions for these rules? Cumulatively, the impact has not even been mentioned in any regulatory packet: federal or state. Yet, independently these regulations will force businesses to sensitize the general public into complete paranoia with four separate right-to-know procedures for compliance(five when 40 CFR part 68 goes on the books).

Your task is an important one. Risk assessment has been at the center of concern for our Council for some time. Again, we appreciate the opportunity to comment at this time and are available for future cooperation on this matter.

Respectfully:

W.E. "Walt" Murray
Executive Director
M.C.C.V.

NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE

January 31, 1994

Dear Representative:

This week the House of Representatives is scheduled to consider H.R. 3425, the Department of Environmental Protection Act, a bill to elevate the Environmental Protection Agency (EPA) to cabinet level status. The proposed rule on the legislation, however, does not provide an opportunity for you to fully address the role of risk/benefit analysis when regulations are promulgated by this new cabinet level department.

The importance of a risk/benefit analysis requirement on EPA has recently been underscored by a well meaning but burdensome regulation with significant negative impact on agricultural production. The Agency developed a new Worker Protection Standard (WPS) for Agricultural Pesticides which is schedule to go in effect on April 21, 1994. While the purpose of the program — protecting farmworkers from pesticide exposure — is laudable, the WPS as currently designed is so complex and ill-conceived that we as state regulators cannot possibly enforce the standard on April 21, 1994.

Even though we as state regulators have been joined by farmers and Members of Congress — including Senate Appropriations Report language — calling for a delay in the implementation date, EPA refuses to recognize the problems it has created and delay the date of implementation. And even more astounding, they refuse to change the date even though there is no legislative mandate to implement the program on April 21.

This recent example provides strong indication that Congress will need to mandate a risk/benefit analysis before EPA — or a cabinet level department — will consider how their regulations impact the real world.

On behalf of the Commissioners, Secretaries and Directors of Agriculture in the fifty states and four territories, I encourage you to insist on a risk analysis amendment to H.R. 3425 before the House of Representatives approves EPA's elevation.

Sincerely,

Mark C. Nestlen
Manager, Legislative & Regulatory Affairs

Richard W. Kirchhoff, *Executive Vice President & Chief Executive Officer*

1156 15th Street, N.W. Suite 1020 Washington, DC 20005 (202) 296-9680 (202) 296-9686 fax

STATEMENT OF SENATOR J. BENNETT JOHNSTON

February 1, 1994
Hearing before the Subcommittees on
Environment, Energy and Natural Resources,
and Legislation and National Security,
of the House Committee on Government Operations

Mr. Chairman, members of the Committee, thank you for the opportunity to testify on risk-based environmental decisionmaking, particularly with respect to the pending legislation that would make the Environmental Protection Agency a cabinet department.

I start from the premise that we must do a better job of setting environmental priorities. In the face of ever-tightening budgetary constraints, it has become increasingly apparent that we must focus our limited resources on the environmental problems that pose the greatest risk. And that means making choices, many of which will not be popular with some of our constituents, but which are necessary if we are to get the most for our environmental protection dollar.

I believe that those choices should be guided in large part by a ranking of the various risks posed, based on the best scientific information available. EPA recognized this in its seminal 1987 Unfinished Business report, where EPA systematically ranked the seriousness of the various risks that it was addressing or could address. The report found that there was little correlation between the risks that the EPA staff judged as most threatening and EPA's program priorities. Instead, EPA found a correlation between EPA's priorities and public opinion on the seriousness of various environmental threats. "Overall, EPA's priorities appear more closely aligned with public opinion than with our estimated risks."

These conclusions were confirmed in 1990 by EPA's Science Advisory Board in its Reducing Risk report. Reducing Risk urged EPA to target its environmental protection efforts on the basis of opportunities for the greatest risk reduction.

I recognize that Congress is part of the problem. Perhaps because of Congressional mistrust of EPA over the last 12 years, we have written statutes that constrain EPA's ability to set rational environmental protection priorities. I believe that we must review those statutes and remove barriers to rational priority-setting.

But that is a subject for future hearings. Today, I want to

discuss the need for concise, readable information about the risks addressed by individual environmental regulations. Regulations are where the "rubber meets the road," where billions of dollars are spent in the pursuit of a specific environmental solution. Unless we clearly understand the effects of significant regulations, we will be unable judge whether we are addressing high-risk problems in cost-effective ways, or low-risk problems in wasteful ways.

My amendment is intended to address this part of the problem, and it can be summarized quite briefly. First, it would require the Secretary to estimate the risk addressed by a regulation and the cost of implementing that regulation. Second, it would require the Secretary to compare the risk addressed by the regulation to other risks to which the public is exposed.

Finally, it would require the Secretary to make a certification of certain matters, or explain why she is unable to so certify. The Secretary is asked to certify that the estimates and comparisons are based on the best available scientific data, that the regulation will advance the purpose of protecting against the risk identified, and that the regulation will produce benefits that justify the cost of the regulation. If the Secretary is unable to make this certification, she need only explain why.

Although the amendment received near-unanimous support in the Senate, some House members and others have expressed concerns, which I would like to address. One concern has been that the amendment would increase the costs of promulgating new regulations. On this point, the Congressional Budget Office has estimated that the amendment would add $20 million annually to EPA's cost of issuing regulations. However, CBO also concluded that the amendment would result in no significant additional costs for the promulgation of major rules. In other words, the $20 million is caused by applying the amendment to rules that are not major.

I want to assure you that I am amenable to limiting the size and type of regulations that are subject to the amendment, and look forward to resolving that issue in conference. I am confident that we can reduce the cost of implementing the amendment to an amount that is quite small, particularly in comparison to the huge costs of complying with a major rule.

Another concern has been that the amendment would delay the rulemaking process. For example, some have suggested that the amendment would require the Secretary to compare the risk addressed by the regulation to every imaginable risk to which the public is exposed.

This concern should be satisfied by a close reading of the

amendment; it says that the Secretary shall compare the risk addressed by the regulation "to other risks to which the public is exposed." It does not say that the comparison should be to all risks to which the public is exposed.

Furthermore, the purpose of the risk comparison is very simple; it is to give members of the public some understandable reference points so that they can grasp the magnitude of the risk posed. Most of us cannot immediately grasp the meaning of a ten to the minus six chance of dying from a particular ailment. But if we can compare that risk to three other common risks, such as the risk of dying from lung cancer, the risk of dying in a car accident, and the risk of being hit by lightning, we can have some idea of what the scientists are talking about. That is all that the amendment calls for. If the Secretary believes that this can be accomplished by using the same three common examples in every regulation, I would have no objection.

In fact, the amendment does not require any new fact-finding studies prior to promulgating a regulation; that is why it asks the Secretary to certify only that the scientific evaluation of the risk be based on "the best available data." If the Secretary bases her assessment of risk and costs and benefits on the scientific information available to her at the time the regulation is issued, the amendment is satisfied.

Delay from litigation is also precluded. The amendment provides that actions called for by the amendment are not subject to judicial review. The amendment provides that it "shall not be subject to judicial review," and that "Nothing in this section shall be construed to grant a cause of action to any person." We need better environmental regulations, not more litigation.

In the same vein, I noticed that H.R. 3425 provides that "This section [section 114, regarding unbiased scientific information] shall not be the basis for challenging actions taken under other provisions of law, or the cause of delay of any action required to meet a statutory or court-imposed deadline." If adding a provision similar to this to my amendment would give members of the House comfort, I would be happy to consider such an addition in conference.

There are a few other misconceptions about the amendment that I would likely to briefly clear up. First, the amendment does not change existing environmental laws. That is why it says that "this section shall not be construed to amend, modify, or alter any statute...." If an existing environmental law requires the Secretary to issue a regulation that involves huge costs and minimal benefits, the amendment does not relieve her of that obligation. But it does give her an opportunity to say "Congress, the benefits of this regulation do not justify the costs, but you made me do it," and I think that's valuable

information.

Second, the amendment does not require the use of a particular method of risk assessment. I realize that risk assessment is an evolving scientific field, and the last thing I want to do is impede that progress.

Third, the amendment does not require that the Secretary certify that the benefits exceed the costs. Instead, the amendment asks the Secretary to certify that the benefits justify the costs. I used "justify" rather than "exceed" because it is difficult to estimate costs and benefits, and I wanted to give the Secretary significant latitude on this matter. If the Secretary finds it difficult to estimate the benefits of a particular regulation, but she concludes that those benefits justify the costs involved, the amendment allows her to enter a positive certification.

Finally, the amendment does not limit the authority of the Secretary to regulate. As long as the Secretary is willing to explain why she did not make a certification, she can issue any regulation she deems appropriate. That is why the amendment is a "truth in labelling" provision. It requires candor, but it does not constrain the regulatory discretion of the Secretary.

I would also like to address the two arguments that the Administration has made against the amendment. First, the Administration has said that it wants a "clean" bill i.e, one limited to administrative provisions. Although that may be the Administration's preference, the Senate has already rejected that approach. When the Senate debated S.171, the first amendment considered was a clean substitute offered by Senator Roth, and it was voted down. The Senate then went on to add several substantive provisions, including the one I offered.

The Administration also argues that my amendment should be set aside so that the Administration's September 30, 1993 Executive Order can be given a chance to work. I find this unconvincing for several reasons.

First, the Clinton Executive Order is limited almost entirely to assessing costs and benefits, and has very little to do with assessing the risk addressed by a particular regulation. Specifically, section 6 of the Executive Order, which sets forth the actual process for adopting regulations, does not require that a risk assessment be performed in conjunction with the promulgation of a regulation. It merely requires that costs and benefits be assessed.

Instead of requiring risk assessment in section 6, risk-based prioritization is listed in section 1 as one of twelve general regulatory principles that agencies "should" follow.

Section 4, regarding annual regulatory plans, requires consideration of risk, but only with respect to "the most important significant regulatory actions," whatever that means.

Thus, the Executive Order lacks important elements that are contained in my amendment. Under the Executive Order, regulations need not be accompanied by a plain and simple statement regarding risk. The risk addressed by the regulation need not be estimated, and it need not be compared to other risks to which the public is exposed. Similarly, there is no requirement for a certification that the best available scientific data was used, or that the regulation will advance the purpose of protecting against the identified risk, or that the benefits justify the costs of the regulation.

In addition, the Executive Order provides that OMB can exempt regulations from even the required cost-benefit analysis. Although the Administration has said that it will make only limited use of this exemptions, the actual language of the Executive Order is entirely open-ended.

Finally, no Executive Order can do the job of a statute. We have had an Executive Order that requires cost-benefit analysis since 1981, but it has brought us no closer to establishing risk-based environmental priorities. The Clinton Executive Order is fine as far as it goes, but it does not go nearly far enough. It is time for Congress to address this issue itself, and I can think of no better place than in a statute that will guide our new Department of Environmental Protection.

In closing, Mr. Chairman, I want to thank you for holding this hearing. We have just begun the process of setting environmental priorities based on relative risk, and I pledge to work with you for as many years as it takes to get the job done.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D C 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

MAR 31 1994

Honorable John L. Mica
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Mica:

As follow-up to the February 1, 1994 hearing on risk based decision-making, you asked me to clarify my position on a number of questions. Enclosed are my responses to those questions.

I look forward to continuing to work with you and your colleagues on the important issue of risk analysis.

Sincerely yours,

Sally Katzen

Sally Katzen

Enclosure

Follow-up questions from Representative Mica
February 1, 1994 Hearing on Risk Based Decision-making

1) Recognizing that state and local government organizations, such as the League of Cities, the Conference of Mayors, and the National Governor's Association, strongly support risk assessment and cost/benefit analysis as necessary means for addressing the problems of unfunded mandates and acknowledging that President Clinton has vowed to assist State and local governments with unfunded mandates, does the Administration support risk assessment and cost/benefit analysis for EPA regulations? In addition, does the Administration support the language in the "Johnson Amendment?"

As I testified at the February 1, 1994, hearing, the Administration believes that risk assessment and cost-benefit analysis are effective tools for regulatory decision-making, not just within EPA, but within all Federal agencies. The Executive Order on Regulatory Planning and Review (E.O. 12866), signed by the President on September 30, 1993, underscores the importance of rigorous analysis. The Executive Order specifically directs agencies to consider the costs and benefits or a proposed regulation, as well as how the proposed action would reduce risks to public health, safety or the environment.

As you know, the Administration opposed the Johnston Amendment to the EPA Elevation bill. I testified that the language was both overinclusive and underinclusive. It is overinclusive in that it would require risk analysis for <u>all</u> EPA regulations -- even routine regulations where such analysis would not be particularly useful. The amendment is underinclusive in that, unlike our Executive Order, it applies only to EPA and not to all Federal agencies that regulate health, safety and environmental risks.

2) Executive Order 12866 says that agencies must use the best available scientific data to assess the need for and consequences of a rulemaking. Will the Administration interpret "best scientific data" to mean that risk assessments should present the most scientifically plausible estimate (or a "best estimate") along with associated uncertainties?

The Executive Order uses the term "best reasonably obtainable scientific...information". We contemplated that the agencies would use valid data relevant to the task at hand and reasonably available. As a general matter, the decision maker should be given not just a single number (whether the "most scientifically plausible estimate" or "best estimate") but a full range of data points with as much information as is useful to reveal the underlying assumptions and the degree of uncertainty that may exist.

3) In view of the limited resources, should risk assessment be used as a tool to set priorities and should objectives and unbiased risk assessment be used to set those priorities in order to ensure that we do not mis-allocate scarce funds?

Risk analysis is certainly one of several tools that should be used in setting priorities. As I have testified, however, an agency often does not have discretion in setting its priorities because Congress has assigned it specific tasks, to be complete in defined time frames, and these mandates should be honored -- even it the agency decides that other tasks would be more productive in reducing health, safety, and environmental risks. Where agency resources are limited, as they increasingly are, the statutory mandates may be the only items that the agency can address.

4) How much does the Administration estimate the cost will be to conduct Department of Energy and Department of Defense facility clean-up programs?

We do not have a precise estimate of the cost of conducting Department of Energy and Department of Defense facility clean-up programs, but we know that the cost will be very high. In 1991, the Department of Defense released an estimate of overall cleanup costs in the range of $25 billion; the Department of Energy has never prepared such an overall cost estimate, but in testimony before Congress, DOE officials have offered the judgment that the cost will be over $100 billion. The Department of Defense is currently completing a new estimate of the cost of its cleanup program, based on updated information about its cleanup requirements, which is expected to be available during FY 1994. The Department of Energy is currently undertaking a study of its potential total cleanup costs, which was required by the 1993 Department of Defense Authorization Act and which is expected to be completed in FY 1995. The results of both studies will need to be interpreted and used with care, since the range of estimates produced will depend significantly upon the assumptions on which the estimates are based. Assumptions adopted in the studies about factors such as the extent and nature of the contamination problems to be addressed, the timing and level of cleanup, cleanup standards, technology available and utilized, and the cost of cleanup labor and technology, among others, will have a significant impact on the range of cost estimates resulting from the studies.

Notwithstanding the departments' attempts at developing a cost estimate, the Administration places a higher priority on addressing the clean-up needs than on developing a precise cost estimate.

5) Recently, the EPA issues a new regulation which requires onboard refueling controls on trucks. In that case, the American Medical Association had written to Congress and said that any health benefits of such regulations would be "inconsequential," yet apparently a major part of EPA's justification for the regulation was that it would have important health benefits. It appears that EPA's assessment of benefits under the Executive Order in this case must have been based on worst-case risk assessment and tenuous data or hypotheses rather than the "best available data." Please explain this decision-making process in observance of the Executive Order.

EPA presented a number of reasons for requiring on-board refueling control for trucks. The health benefits (in terms of reduced cancer cases) was only one of the factors cited by EPA. The primary reason was that EPA's analysis indicated that onboard refueling control represents a cost-effective means of achieving reductions in ozone-forming emissions. The OIRA staff that reviewed the analysis supporting the regulation found it to be at or above the level of analysis expected from the agencies.

6) The National Performance Review is entitled "Creating a government that works better and costs less." If the Administration is serious about reducing the size of the federal government as well as its costs, why then is it not required that cost benefit be used uniformly and consistently in the promulgation of regulations?

As I have previously testified, while the Administration supports cost-benefit analysis, it does not believe that one size fits all' and that indeed the benefit of doing a cost-benefit analysis in some instances (e.g., routine or nondiscretionary regulations) may not justify the costs of doing a cost-benefit analysis. The NPR underscored the importance of tailoring solutions to the particular problem rather than imposing a single set of command and control regulations on all agencies.

7) The EPA report entitled "EPA's Use of Benefit-Cost Analysis 1981-1986" found that benefit-cost analysis frequently provides the basis for stricter environmental regulations and may reveal regulatory alternatives that achieve the desired degree of environmental benefits at a lower costs. Please comment on this.

The purpose of developing the benefits and costs of regulations and reasonable alternative actions under Executive Order 12866 is to develop smarter/better regulations. In some cases this may mean the identification of a more stringent (but cost-effective) regulatory alternative as suggested by EPA's report ("EPA's Use of Benefit-Cost Analysis 1981-1986"), and in some cases it may identify a less stringent regulatory action (e.g., labeling) as a desirable alternative (depending on the statutory authority/framework).

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

MAR 31 1994

Honorable Karen L. Thurman
U.S. House of Representatives
Washington, D.C. 20515

Dear Congresswoman Thurman:

When I testified on February 1, 1994, on risk analysis before the Committee on Government Operations, you asked me to give "examples where the Executive Order [on Regulatory Planning and Review] has worked" to save localities money.

I believe the Executive Order has had the salutary effects that it was intended to have. I must emphasize that if the process works perfectly, someone in my position would not be aware of each and every change in a regulation -- from initial concept through the development of a Notice of a Proposed Rulemaking through the preparation of a final regulation. As you know, the agencies are the entities primarily responsible for implementing the principles set forth in the Executive Order, and to the extent they do their jobs, the reviewing entity would not be aware of what would have been done in the absence of the Order.

We have, however, seen an increase in sensitivity to the issue of unfunded mandates and attempts to minimize the burdens on State, local, and tribal governments.

Three recent examples are:

- a Department of Health and Human Services proposal to establish standards for the development of statewide information systems enabling States to track information on the status of every child in foster care. We worked with the agency to allow States the option of providing a sample -- rather than 100 percent -- of the data, thus greatly reducing state reporting requirements; and

- a Department of Education proposal to provide more flexible regulatory standards in assessing educationally disadvantaged children who receive services related to their education. While States currently must meet detailed regulatory standards, under the new proposal, States will be allowed to develop their own testing methodologies that are consistent with their education reform efforts.

- an Environmental Protection Agency policy to control combined sewer overflows that occur in older cities when a municipal treatment plant cannot treat both the storm water runoff and domestic sewage during heavy rains. One of the options discussed could have cost municipalities as much as $14 billion per year. Instead, the final policy provides flexibility to municipalities to tailor programs based on the site-specific pollutant reductions achieved and the costs of alternative control options.

As agencies implement the principles of the Executive Order, we expect to see increasing evidence of the ways they work to save localities money.

I hope this has been responsive to your inquiries.

Sincerely yours,

Sally Katzen

cc: Honorable John Conyers, Jr.

Identical Letter Sent to Honorable John M. McHugh

Congresswoman Corrine Brown
February 1, 1994
Supporting H.R. 3425
Department of Environmental Protection Act

Mr. Chairman, I strongly support H.R. 3425, the Department of Environmental Protection Act, and applaud you for holding this hearing today on risk assessment. I would also like to commend the President for giving us some real leadership on this issue. This long overdue legislation demonstrates our nation's commitment to the environment at the highest levels of our government. This bill places environmental considerations in the highest forum -- the President's Cabinet -- where our country's policies and decisions are made. This bill also promotes our nation's environmental interests within the international community and promotes international cooperative efforts to address global environmental issues.

The Committee has crafted a good clean bill that is free from substantive policy language but does address the organizational changes necessary to elevate the agency to cabinet status. The goal of this bill is to achieve organizational, structural and management reforms; it is not designed to legislate environmental policy. This legislation should not be used to change existing environmental statutes under the jurisdiction of other committees.

Elevating EPA to the top tier of the U.S. government as an equal member of the President's Cabinet of advisors must happen before we consider other environmental legislation such as the Clean Water Act, Safe Drinking Water Act, and

Superfund. Cost/benefit, risk analysis, takings/private property rights, wetlands or other issues that affect existing environmental statutes go beyond the scope of this bill. There are other opportunities and legislative vehicles to address these substantive environmental policies.

Our Cabinet Elevation Bill accomplishes several important administrative goals to correct a number of problems at the agency, particularly contracting problems. The bill contains reforms in managing privately contracted work and equipment procurement by the department. EPA has been severely criticized for mismanagement of contracted work, resulting in wasted money and missed objectives. This bill would curb umbrella contracting and contract shopping. The bill would prohibit contractors from performing government functions such as audits and financial oversight of projects.

For the first time, there will be an Office of Environmental Justice to address concerns that minority groups and the poor face disproportionately high health risks from pollution. There is growing concern that low-income and minority communities are face higher exposure rates to certain toxins and polluting facilities. This bill will also create an Office of Environmental Risk to reduce risks to human health in our environment.

This bill provides the structural changes needed to elevate the EPA to Cabinet status. Thank you.

OPENING STATEMENT OF JOHN CONYERS, JR.
CHAIRMAN,
SUBCOMMITTEE ON LEGISLATION & NATIONAL SECURITY
HEARING ON RISK ASSESSMENT ISSUES AT EPA

FEBRUARY 1, 1994

Good morning, today the subcommittees come together to examine the important issues of risk assessment and cost-benefit analysis in the context of agency rulemaking. The issue, to say the least, is somewhat new and somewhat thought-provoking.

The Chair wants to make special note of the contributions which Gary Condit, a Government Operations Subcommittee chairman, has made on this subject, and wants to thank Subcommittee Chairman Mike Synar and the able subcommittee staff for putting together this subcommittee hearing with such speed and skill.

We all recognize that there sometimes appears to be an unfairness about the regulations that are drafted by EPA and other agencies by perhaps putting too much burden on small communities and industry for what seem to be small achievements. On the other hand, we also know that there are huge and often multiple environmental problems facing all parts of this country which need to be addressed, and which are unwise to pit against each other. The question is are we striking the right balance.

In striking that balance we want to ensure that we do not create a new bureaucracy which creates significant unforeseen consequences. Does the creation of a risk assessment scheme, complemented with a cost-benefit analysis, increase public health problems by forcing us to pit one problem against another when protecting public health? Should agencies compare risks regulated by other agencies over which they have no control? Should Congress be in the business of micromanaging a risk assessment program which EPA and other agencies are already implementing through Executive Order 12866? Is cost-benefit analysis sound science? And are there other ways of addressing regulations which unfairly and unwisely burden certain populations?

There is widespread recognition on both sides of this issue that answers to these questions are not easy. That is why I and others have opposed attempting to address this in legislation which is before the House at this time, and why I thank others for their willingness to engage in closer scrutiny before legislating in this area.

I look forward to our witnesses answering these and other questions so that the members of the Committee on Government Operations can have a more informed discussion of these issues, and so that we don't legislate blindly.

OPENING STATEMENT BY CONGRESSMAN CRAIG THOMAS
HEARING ON RISK ASSESSMENT
FEBRUARY 1, 1994

Mr. Chairman:

I would like to thank you, Mr. Chairman, for holding this hearing on risk assessment and for allowing me the opportunity to participate today. Although I'm not a member of the Subcommittees involved in this hearing, I have a great interest in this issue as a member of the full committee and I appreciate the opportunity to listen to the testimony today.

Across the state of Wyoming, I have witnessed first-hand one small town after another become entangled in the bureaucratic machine EPA has become. Throughout time, EPA has arisen to become a giant regulation treadmill, forcing one court-ordered regulation after another down the throats of small businesses who can least afford these requirements.

I represent a state of 450,000 people and would have to search long and hard to find a business, community or local government that hasn't been threatened by the EPA. I could spend hours talking about the Town of Pinedale which, despite a water system that cleans and purifies it's water better than the bottled water we use in our offices, will be required by EPA to spend millions of dollars it doesn't have, for chlorination and filtration regulations. Only 1,118 people live in Pinedale but they will have to pay $1.5 million dollars to solve a problem this rural water system doesn't have. If an Office of Environmental Risk and Cost Analysis were implemented, many businesses and local communities like Pinedale would find reason in EPA and restore their faith in the federal government.

Solid waste regulations or (Subtitle D regulations) are further examples of mandated regulations. These nationwide regulations have flood control requirements for municipalities as diverse as New York City and Basin Wyoming. Whether a city has 50 inches of rainfall or 5 inches of rainfall, the regulations are the same.

The result of subtitle D regulations has been the forced closure of small rural landfills. For example, in Chugwater, Wyoming (Population 493) it's landfill was closed, however, the volume of trash dumped in gullies and ravines has increased. In this instance, federal regulations have caused greater pollution for the community of Chugwater.

In my hometown of Casper, Wyoming, high school students were forced our of their school by the EPA, and forced to attend school at night and in other buildings for a year and a half while over a million dollars was spent to free the building of asbestos. All this so the EPA could come back a year later and tell the students and citizens of Casper that it wasn't much of a

threat to begin with.

Because of these and many other examples, Mr. Chairman, I support the proposed Office of Environmental Risk and Cost Analysis. EPA should be held accountable for the costs, and benefits of regulatory proposals in order to achieve greater reductions in pollution at lower costs.

EDOLPHUS "ED" TOWNS
MEMBER OF CONGRESS
10TH DISTRICT, NEW YORK

ENERGY AND COMMERCE
HEALTH AND THE ENVIRONMENT
COMMERCE, CONSUMER PROTECTION AND COMPETITIVENESS

GOVERNMENT OPERATIONS
ENVIRONMENT, ENERGY AND NATURAL RESOURCES
CHAIRMAN
HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS

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Opening Statement

REP. ED TOWNS

"Risk-Based Decision-Making at the E.P.A."

Subcommittee on Environment, Energy and Natural Resources

1 February 1994

I want to commend you, Mr. Chairman, for holding this hearing and bringing together this impressive group of witnesses to testify. I have two concerns about risk assessment which I will touch on here.

First is that risk assessments should be communicated to the public in an open fashion. This hearing should make clear the complex calculations that can go into a risk assessment, and when they are done by the government, people naturally assume that they are going to be used in formulating government policy. Therefore, it is incumbent on the government to make clear what goes into these calculations, to lay them out for public scrutiny, so that the public can have confidence in the numbers that undergird our policy choices.

We have heard from several sides that risk and policy are not well-matched, that we are spending too much on concerns of low risk and too little on concerns of high risk. Yet it is obvious to me that we cannot rely on risk assessments which arrive, like manna from heaven, with very little explanation of how they came to be. Unlike the donator of manna, the public is naturally suspicious of who produces these numbers. A complete disclosure of how a risk assessment was done, what assumptions, science, and analysis went into it, would go far to gain public confidence -- unless the system is riddled with flaws, in which case we certainly need to know that, too. If it has flaws, then making that public will encourage research into those areas of ignorance or flawed analysis, and should give us a greatly improved tool for the future.

In sum, I see full disclosure of how risk assessments are done as a means to instill public confidence in the final conclusion, or to make obvious how far we are from making accurate, quantitative statements about the risks in our environment. In either case, we should improve how we formulate policy and how we set priorities.

That is my second point, that we should set our policy on a strong foundation. If risk assessment is such a foundation, then let us use it as one of several tools to set policy. If it is not, then let's stop deluding ourselves that there is some obvious path to an objective standard. Let's not pretend that we all get up in the morning and assess how risky it is to walk or drive to work, but if we can, let's make comparisons within our environmental laws so that we spend the most money to protect public health in those areas where people are most at risk.

The immediate question is when and how Congress should address this issue. It has arisen in the course of debate on elevating the Environmental Protection Agency to cabinet status. These two issues come out of very different policy concerns, one over the domestic and international status of the EPA, and the other over how the federal government communicates its work to the public. The Committee on Government Operations has already reported our elevation bill to the House, and, while I certainly hope the Congress will address the risk assessment issue, I do not see the wisdom of trying to do them together.

Thank you again, Mr. Chairman, for calling this hearing, and informing us about this issue.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 22 1994

Honorable Mike Synar
Chairman
Subcommittee on Environment, Energy
and Natural Resources
Committee on Government Operations
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Chairman:

This is in response to your June 16, 1994 letter to Lynn Goldman, Assistant Administrator for Prevention, Pesticides, and Toxic Substances, containing Rep. Hayes' questions following up on the February 1, 1994 hearing on risk-based decision making at EPA.

Our responses to Mr. Hayes' questions, prepared by the Office of Pollution Prevention and Toxics, are attached. If I can be of further assistance, please let me know.

Sincerely,

Robert H. Hickmott
Associate Administrator

The Toxic Release Inventory (TRI) is a powerful and cost-effective program. Data generated by the TRI process is used by environmental and citizen's groups to highlight polluters.

Unfortunately, the current program does not make a distinction between low-volume, highly toxic "releases" and the "release" of high-volume wastes that are non-toxic in whole or part, or are relatively non-toxic. Since no distinction is made, companies that have high-volume, low-toxicity releases are forced to invest in equipment to reduce the volume of wastes generated, thereby reducing their ability to commit capital where it may be needed.

Q. 1. Does EPA have any views with regard to revising the TRI to reflect relative toxicity of the substances classified as "releases" under the statute (Emergency Planning and Community Right To Know Act)?

A. 1. The current Toxics Release Inventory (TRI) is a listing of chemicals taken from reporting lists from the states of Maryland and New Jersey. Congress combined the two lists as EPA's starting point for the TRI program. Congress also provided EPA with statutory criteria to be used to add or delete chemicals from the list.

The criteria applied to the TRI list addresses acute and chronic human and environmental toxicity. The criteria are sufficiently broad that there is a range of toxicity reflected by the chemicals on the list. That toxicity ranges from moderate to high.

The data on chemical releases and distribution within the environment provided by the TRI has always been characterized by EPA as a pointer or spotlight on where to look for potential areas of concern. Only when the data are linked with specific toxicity and exposure information does it become an indicator of risk. Consequently, chemicals with moderate toxicity but with high release and exposure potential could be of equal or more concern than a high toxicity chemical that may have low releases and a relatively small exposure potential.

EPA does not believe that there is a good way to differentiate between chemicals in the actual reporting system itself. We can, however, draw distinctions between chemicals when we release the data to the public. We have made an effort to distinguish between types of chemical hazards (e.g., identifying known carcinogens) in the outreach materials we give to the public. We are looking at ways to improve these characterizations of the data.

Q. 2. I note that EPA recently proposed the addition of 313 new substances to the TRI. What is EPA doing to delist certain substances that do not belong on the TRI?

A. 2. EPA has deleted from the TRI list 13 chemicals and one large chemical category that it has determined do not meet the toxicity criteria of TRI. The statutory petition process has allowed the opportunity for these refinements to occur.

Q. 3. In particular, what is EPA doing about the proposed regulation to delist ammonium? After all, the regulation to delist ammonium was first proposed in 1990 -- when will the EPA make a decision and go final?

A. 3. The delisting of ammonium sulfate has proven to be the most complicated and controversial of all the petitions that EPA has received. It involves not just the delisting of one particular compound but raises major science policy issues for ammonia as a category of compounds. At issue is the relative toxicity of ionized vs. un-ionized ammonia and the predictable concentrations of each that will be present under varying environmental conditions.

The Agency is close to resolution of these issues and plans to announce its decision by late summer.

Additional Questions and Answers
Re February 1, 1994 Hearing
Sally Katzen
Administrator, OIRA

Question:

One of the objections to the TRI program is that it does not discriminate between low-volume toxic releases and high-volume non-toxic or low-toxic releases. Clearly, there is a negative impact to the economy if the TRI list is not accurate; public pressure forces companies to spend money reducing the generation of listed chemicals that are not toxic. As a result, companies don't spend money on reducing truly toxic wastes or, worse, decide to close the plant in question. How does OMB review TRI additions and deletions? How did the OMB approach the recent listing of the 313 additions?

Response:

OMB reviews additions and deletions to the Toxic Release Inventory (TRI) list according to the procedures outlined in Executive Order No. 12866. If a proposed TRI action is a significant regulatory action as defined by the Executive Order, OMB reviews EPA's determination that the action is consistent with the principles of E.O. 12866. With respect to the recent notice of proposed rulemaking to expand the number of chemicals on the TRI list, EPA estimated that its proposal would have annual costs in excess of $100 million, thus satisfying a criterion for OMB review under the Executive Order. During OMB review, we asked the kinds of questions that we typically raise in reviewing a proposed rule, including the economic effect of the additional reporting requirements on firms. This and other issues were included in the preamble of the notice to elicit comment from the public. Such public comment on the proposal should assist EPA and OMB's assessment of whether the draft final rule is consistent with the principles of E.O. 12866.

Question:

In 1990, the EPA proposed a regulation to change the way ammonia releases are reported under TRI. One of the alternatives was to allow the reporting of unionized ammonia only. When will the OMB and EPA release the final regulation? Are you considering the economic impacts?

Response:

EPA has not submitted a draft final rule on this issue for Executive Order review. When EPA submits an action, OMB will conduct a full review under the procedures and principles of E.O. 12866, including the economic effect of this reporting requirement.

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Chairman

Howard Dean
Governor of Vermont
Vice Chairman

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Executive Director

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February 17, 1994

Honorable Mike Synar
Chairman
Subcommittee on Environment, Energy, and Natural Resources
B-371C Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

As I mentioned in my statement at the February 1, 1994 hearing on risk assessment, I would like to submit the enclosed policy for inclusion in the hearing record. The policy statement was adopted by the governors at the National Governors' Association (NGA) Winter Meeting on February 1, 1994.

Also, in response to Representative Thurman's request, I am submitting the list of twenty-six states involved in comprehensive environmental strategic planning as reported in a 1991 National Governor's Association (NGA) survey.

These states are as follows: Alabama, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Missouri, New Mexico, North Carolina, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Vermont, Virginia, and Washington

The study found considerable and growing interest in strategic planning, so we expect that a current survey would show even higher state involvement. The study did not address program-specific or regulation-specific risk assessments. These also are accepted tools used by state agencies, but NGA, unfortunately, does not have data on the extent of its use in the states.

Rep. Mike Synar
February 17, 1994

I appreciated the opportunity to convey the Governors' views on this important subject and hope you will feel free to contact me or the staff at NGA with any further questions.

Sincerely,

Randolph Wood
Director of Environmental Quality
State of Nebraska

Enclosure

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NR-8. ENVIRONMENTAL PRIORITIES AND UNFUNDED MANDATES

8.1 Preamble

The nation's Governors are committed to protecting public health and conserving the environment for the American people. The Governors strongly support and are committed to achieving the national environmental goals outlined by Congress in recent decades. The successful implementation of many environmental programs at the state level demonstrates the Governors' significant contribution to environmental protection. In order to further environmental progress in the states, the Governors pledge to continue working with Congress and the administration on the development of new or revised federal environmental programs.

8.1.1 **Costs of Environmental Protection.** Yet the Governors are deeply concerned about the high and growing costs of environmental protection, including both the programmatic and capital costs required to comply with federal environmental mandates. These costs, borne by states, local governments, and the private sector, result in part from new federal requirements related to air, drinking water, water quality, and waste management that require substantially more sophisticated programs and additional environmental infrastructure throughout the nation.

8.1.2 **Reduction of Unfunded Mandates.** The Governors also are committed to reducing unfunded federal mandates, including environmental requirements. Although many environmental requirements have merit, the cumulative effects of unfunded mandates challenge states either to fund the federal requirements from very limited revenues or to divert funds from other state priorities. Therefore, the Governors believe that Congress must provide adequate resources to fund mandatory environmental programs.

In this era of reinventing government, the federal government and the states must commit to a new partnership for environmental protection that aggressively promotes high standards of performance — not bureaucratic processes. All levels of government must stress the importance of maximizing efficiency in the use of available resources, in order to work more effectively for the protection of the environment. In turn, the Governors call upon the federal government to commit to the following important principles.

8.2 Principles

8.2.1 **Federal environmental laws and regulations must recognize the need to set priorities and focus on the most important environmental objectives at the national, state, and local levels.** In order to promote risk-based priority setting, environmental requirements should be based upon sound science and risk-reduction principles, including the appropriate use of cost-benefit analysis that considers both quantifiable and qualitative measures. Such analyses will ensure that funds ex-

pended on environmental protection and conservation address the greatest risks first and provide the greatest possible return on investment.

8.2.2 **The federal government must discipline environmental legislation and regulation based upon the following criteria.**

- If an environmental problem warrants passage of federal legislation or adoption of regulations, state and local governments should receive federal assistance to carry out the resulting requirements.
- If the federal government does not provide the necessary financial assistance for states to comply with federal environmental mandates, the federal government should allow state and local governments to carry out environmental protection activities based upon their own priorities and programs.
- If new problems emerge that require federal attention but additional federal resources are not available, the federal government should balance existing requirements against new requirements so that the highest priority work can be accomplished within existing budgets.

8.3 **Recent Actions**

The principles of this policy position are consistent with the intent of Executive Order No. 12866 on regulatory development and review, issued by President Clinton on September 30, 1993, and Executive Order No. 12875 on enhancing the intergovernmental partnership, issued on October 26, 1993. The objective of the executive order is to "reform and make more efficient the regulatory process" in order to provide the American people with a "system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society." This policy position also is consistent with the recommendations made in 1990 by the Environmental Protection Agency's (EPA's) Science Advisory Board on the need to address the greatest environmental needs first by setting priorities according to the risk involved. In 1993 the Environmental Financial Advisory Board also offered its support with a recommendation that EPA expand the role of financial analysis in its regulatory development process to facilitate compliance with affordability tests and fiscal plans.

Time limited (effective February 1994-February 1996).
Adopted February 1994.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

MAR 31 1994

Honorable John L. Mica
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Mica:

As follow-up to the February 1, 1994 hearing on risk based decision-making, you asked me to clarify my position on a number of questions. Enclosed are my responses to those questions.

I look forward to continuing to work with you and your colleagues on the important issue of risk analysis.

Sincerely yours,

Sally Katzen

Sally Katzen

Enclosure

Follow-up questions from Representative Mica
February 1, 1994 Hearing on Risk Based Decision-making

1) Recognizing that state and local government organizations, such as the League of Cities, the Conference of Mayors, and the National Governor's Association, strongly support risk assessment and cost/benefit analysis as necessary means for addressing the problems of unfunded mandates and acknowledging that President Clinton has vowed to assist State and local governments with unfunded mandates, does the Administration support risk assessment and cost/benefit analysis for EPA regulations? In addition, does the Administration support the language in the "Johnson Amendment?"

As I testified at the February 1, 1994, hearing, the Administration believes that risk assessment and cost-benefit analysis are effective tools for regulatory decision-making, not just within EPA, but within all Federal agencies. The Executive Order on Regulatory Planning and Review (E.O. 12866), signed by the President on September 30, 1993, underscores the importance of rigorous analysis. The Executive Order specifically directs agencies to consider the costs and benefits or a proposed regulation, as well as how the proposed action would reduce risks to public health, safety or the environment.

As you know, the Administration opposed the Johnston Amendment to the EPA Elevation bill. I testified that the language was both overinclusive and underinclusive. It is overinclusive in that it would require risk analysis for <u>all</u> EPA regulations -- even routine regulations where such analysis would not be particularly useful. The amendment is underinclusive in that, unlike our Executive Order, it applies only to EPA and not to all Federal agencies that regulate health, safety and environmental risks.

2) Executive Order 12866 says that agencies must use the best available scientific data to assess the need for and consequences of a rulemaking. Will the Administration interpret "best scientific data" to mean that risk assessments should present the most scientifically plausible estimate (or a "best estimate") along with associated uncertainties?

The Executive Order uses the term "best reasonably obtainable scientific...information". We contemplated that the agencies would use valid data relevant to the task at hand and reasonably available. As a general matter, the decision maker should be given not just a single number (whether the "most scientifically plausible estimate" or "best estimate") but a full range of data points with as much information as is useful to reveal the underlying assumptions and the degree of uncertainty that may exist.

3) In view of the limited resources, should risk assessment be used as a tool to set priorities and should objectives and unbiased risk assessment be used to set those priorities in order to ensure that we do not mis-allocate scarce funds?

Risk analysis is certainly one of several tools that should be used in setting priorities. As I have testified, however, an agency often does not have discretion in setting its priorities because Congress has assigned it specific tasks, to be complete in defined time frames, and these mandates should be honored -- even it the agency decides that other tasks would be more productive in reducing health, safety, and environmental risks. Where agency resources are limited, as they increasingly are, the statutory mandates may be the only items that the agency can address.

4) How much does the Administration estimate the cost will be to conduct Department of Energy and Department of Defense facility clean-up programs?

We do not have a precise estimate of the cost of conducting Department of Energy and Department of Defense facility clean-up programs, but we know that the cost will be very high. In 1991, the Department of Defense released an estimate of overall cleanup costs in the range of $25 billion; the Department of Energy has never prepared such an overall cost estimate, but in testimony before Congress, DOE officials have offered the judgment that the cost will be over $100 billion. The Department of Defense is currently completing a new estimate of the cost of its cleanup program, based on updated information about its cleanup requirements, which is expected to be available during FY 1994. The Department of Energy is currently undertaking a study of its potential total cleanup costs, which was required by the 1993 Department of Defense Authorization Act and which is expected to be completed in FY 1995. The results of both studies will need to be interpreted and used with care, since the range of estimates produced will depend significantly upon the assumptions on which the estimates are based. Assumptions adopted in the studies about factors such as the extent and nature of the contamination problems to be addressed, the timing and level of cleanup, cleanup standards, technology available and utilized, and the cost of cleanup labor and technology, among others, will have a significant impact on the range of cost estimates resulting from the studies.

Notwithstanding the departments' attempts at developing a cost estimate, the Administration places a higher priority on addressing the clean-up needs than on developing a precise cost estimate.

5) Recently, the EPA issues a new regulation which requires onboard refueling controls on trucks. In that case, the American Medical Association had written to Congress and said that any health benefits of such regulations would be "inconsequential," yet apparently a major part of EPA's justification for the regulation was that it would have important health benefits. It appears that EPA's assessment of benefits under the Executive Order in this case must have been based on worst-case risk assessment and tenuous data or hypotheses rather than the "best available data." Please explain this decision-making process in observance of the Executive Order.

EPA presented a number of reasons for requiring on-board refueling control for trucks. The health benefits (in terms of reduced cancer cases) was only one of the factors cited by EPA. The primary reason was that EPA's analysis indicated that onboard refueling control represents a cost-effective means of achieving reductions in ozone-forming emissions. The OIRA staff that reviewed the analysis supporting the regulation found it to be at or above the level of analysis expected from the agencies.

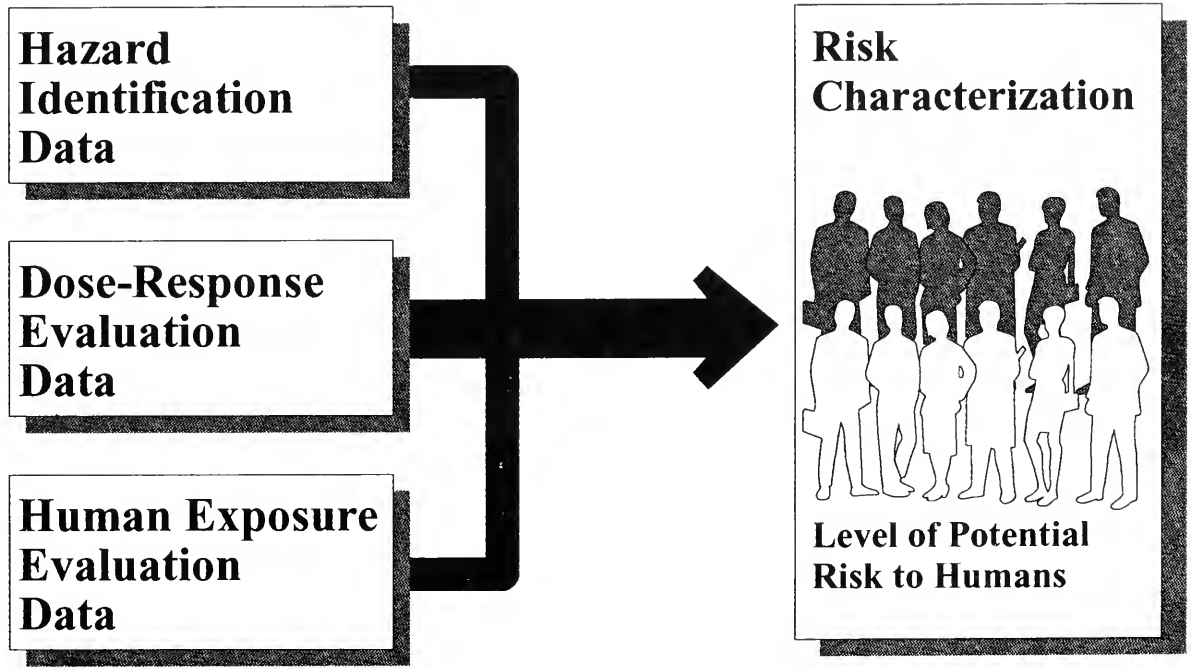
6) The National Performance Review is entitled "Creating a government that works better and costs less." If the Administration is serious about reducing the size of the federal government as well as its costs, why then is it not required that cost benefit be used uniformly and consistently in the promulgation of regulations?

As I have previously testified, while the Administration supports cost-benefit analysis, it does not believe that one size fits all' and that indeed the benefit of doing a cost-benefit analysis in some instances (e.g., routine or nondiscretionary regulations) may not justify the costs of doing a cost-benefit analysis. The NPR underscored the importance of tailoring solutions to the particular problem rather than imposing a single set of command and control regulations on all agencies.

7) The EPA report entitled "EPA's Use of Benefit-Cost Analysis 1981-1986" found that benefit-cost analysis frequently provides the basis for stricter environmental regulations and may reveal regulatory alternatives that achieve the desired degree of environmental benefits at a lower costs. Please comment on this.

The purpose of developing the benefits and costs of regulations and reasonable alternative actions under Executive Order 12866 is to develop smarter/better regulations. In some cases this may mean the identification of a more stringent (but cost-effective) regulatory alternative as suggested by EPA's report ("EPA's Use of Benefit-Cost Analysis 1981-1986"), and in some cases it may identify a less stringent regulatory action (e.g., labeling) as a desirable alternative (depending on the statutory authority/framework).

Risk Assessment Process



How the Public and EPA Rate Health Risks Associated with Environmental Problems

Public		EPA Experts
1.	Hazardous waste sites	Medium-to-low
2.	Exposure to worksite chemicals	High
3.	Industrial pollution of waterways	Low
4.	Nuclear accident radiation	Not ranked
5.	Radioactive wastes	Not ranked
6.	Chemical leaks from underground storage tanks	Medium-to-low
7.	Pesticides	High
8.	Pollution from industrial accidents	Medium-to-low
9.	Water pollution from farm runoff	Medium
10.	Tap water contamination	High
11.	Industrial air pollution	High
12.	Ozone layer destruction	High
13.	Coastal water contamination	Low
14.	Sewage-plant water pollution	Medium-to-low
15.	Vehicle exhaust	High
16.	Oil spills	Medium-to-low
17.	Acid rain	High
18.	Water pollution from urban runoff	Medium
19.	Damaged wetlands	Low
20.	Genetic alteration	Low
21.	Non-haxardous waste sites	Medium-to-low
22.	Greenhouse effect	Low
23.	Indoor air pollution	High
24.	X-ray radiation	Not ranked
25.	Indoor radon	High
26.	Microwave oven radiation	Not ranked

Source: Frederick Allen, U.S. EPA, based on EPA report "Unfinished Business: A Comparative Assessment of Environmental Problems" (1987) and national public opinion polls by the Roper Organization in Dec. 1987 and Jan. 1988.

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